ABSTRACTS OF CASE STUDIES IN THE HEALTH TECHNOLOGY CASE STUDY SERIES

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Preface

This booklet contains a description of the Office of Technology Assessment's (OTA) "Health Technology Case Study Series" and abstracts of each of the case studies published to date.

OTA case studies are designed to fulfill two functions. Their primary purpose is to provide OTA with specific background information that can be used to form general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall assessment *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. However, because of their limited purpose and scope, the case studies should be read primarily in the context of the associated overall OTA assessments.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panels to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e.g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies either are prepared by OTA staff or are commissioned by OTA to be carried out by experts (generally in academia). OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated assessment. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are subjected to external reviews. The reviewers may be from relevant Government agencies; professional societies; consumer and public interest groups; medical practice; and academicians including economists, sociologists, decision analysts, and biologists.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA of each case study's scientific quality and objectivity. OTA does not make recommendations or endorse particular technologies. During the various stages of review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize diverse points of view.

Congressional requesters can receive copies of case studies (if available) by calling OTA. The studies are also available for sale either by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202/783-3238) or the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703/487-4650). Call OTA's Publishing Office (202/224-8996) for availability and ordering information. If you have questions about the series in general or about specific case studies, contact Ginny Cwalina, Series Coordinator in the OTA Health Program (202/226-2070).

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CASE STUDY #1

Formal Analysis, Policy Formulation, and End-Stage Renal Disease

This case study examines the role of formal analyses played in Federal decisionmaking related to end-stage renal disease (ESRD), placing special emphasis on institutional factors encouraging or inhibiting the use of formal analyses. Formal analyses are defined as "any explicitly analytical means of systematically examining the social costs and benefits of alternative policies for the purpose of choosing a preferred alternative in light of an a priori normative decision rule." Cost-effectiveness analysis (CEA) and cost-benefit analysis fit this definition, as do risk-benefit and cost analyses.

The case study deals primarily with the impact of two formal analyses of ESRD issued in 1967: 1) the "Gottschalk report," prepared by an expert advisory committee for the Bureau of the Budget; and 2) the "Burton report," prepared by a Public Health Service task force for the U.S. Surgeon General. It describes policy-related and institutional/bureaucratic factors that led to the conduct of these formal analyses and that affected the form the analyses took, along with many of their methodological assumptions. It also describes and summarizes the results of the CEA in the Gottschalk report and of the "costs and benefits" analysis in the Burton report.

The study then addresses the effects of both reports. The Gottschalk report, for example, led the Bureau of the Budget to fund a Veterans Administration (VA) hemodialysis program that included a substantial portion of the VA dialysis patients. The Burton report, according to the author, had no direct program effects.

On the whole, this case study suggests that formal analysis "did not affect the fact that the policy choice was a basic political choice." It notes, however, that the analyses may have raised the consciousness of high-level policymakers as to cost implications of treatment for ESRD. The case also mentions some of the factors that limit the effect of analysis, such as inadequate data, lack of access of analysts to decisionmakers, and difficulties in making assumptions that frame the problem.

In addition to examining the Gottschalk and Burton reports, this case study presents information on patients with ESRD. It notes that the proportion of men in the total patient population on dialysis declined between 1970 and 1976. The average age of dialysis patients increased, and the proportion of home dialysis patients declined from 40 percent in 1972 to 24 percent in 1976. The number of dialysis patients in the Medicare program rose from 14,000 in 1973 to 50,000 in 1978.

Prepared by: Richard A. Rettig. Published in April 1981 as Case Study #1 of *Background Paper #2: Case Studies of Medical Technologies* (25 pp., 45 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service order #PB 81-209 769.

CASE STUDY #2

The Feasibility of Economic Evaluation of Diagnostic Procedures: The Case of CT Scanning

This case study examines the appropriate methodology for economic evaluations of diagnostic procedures. It develops a framework for analysis, reviews the literature and the cost effectiveness of computed tomography (CT) scanning, and critically evaluates this literature in terms of the evaluation framework.

The case describes a theoretical "ideal" evaluative model that compares the costs and outcomes of alternative diagnostic pathways, each of which begins with the presentation of signs and symptoms and ends with patient outcome. The purpose of the evaluation is not to examine the technology per se, but rather to evaluate its appropriate use. The case describes the need for an appropriate means to: 1) identify homogeneous patient groups, 2) specify diagnostic pathways, 3) measure diagnostic accuracy, 4) measure diagnostic and therapeutic costs, and 5) specify outcomes of the diagnostic and therapeutic process.

In a review of the literature on the economic impact of CT scanning, the case identified only one study that successfully attempted to implement the ideal model of economic evaluation. Most of the other studies examined the impact CT scanning has on diagnostic costs or examined the cost of case finding (also referred to as the cost per positive finding).

The case study addresses efficacy information both for diagnostic studies in general and for CT scanners in particular. Comments regarding the potential benefits associated with negative findings are included.

Costs are distinguished from charges in this case study, and the difficulty of capturing true costs is discussed extensively. Indirect costs are considered. Discounting is not specifically discussed only in the context of the reviewed studies; in one of these, future benefits were discounted. Equity issues are not addressed.

Despite major limitations in applying principles of economic evaluation to diagnostic procedures, the case study concludes that such evaluations are feasible. Some specific uses of CT scanning appear to be cost effective when sufficient demand exists to operate a scanner at full capacity.

Prepared by: Judith L. Wagner. Published in April 1981 as Case Study #2 of *Background Paper #2: Case Studies of Medical Technologies* (24 pp., 47 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 81-209 777.

CASE STUDY #3

Screening for Colon Cancer: A Technology Assessment

This case study examines techniques that are available to screen for colon cancer—their development, evaluation, use, and cost effectiveness. It focuses on the three basic techniques used in the detection of colon cancer: 1) the digital (finger) exam, 2) the sigmoidoscope, and 3) the test for occult blood in the stool. For each method, the case notes, there is some degree of uncertainty regarding the effectiveness of the tests, and some risks to the patient.

The case study points out that there have been few, if any, clinical studies of the digital exam. The sigmoidoscope has been examined in a few uncontrolled clinical studies, and these suggest, but do not prove, its effectiveness in reducing morbidity and mortality. The fecal occult blood test is currently being studied in a number of large clinical trials to evaluate its efficacy. To date, the results are inconclusive.

The study discusses the problems that exist in trying to apply cost-effectiveness analysis (CEA) to colon cancer screening programs. It also examines a number of factors that affect CEA studies in the health care area in general. One is general lack of information from formal randomized clinical trials regarding the effect and value of screening techniques. The information that is available is usually complicated by a number of biases (e.g., lead-time bias, patient self-selection bias, and length bias). The analysis of cancer screening programs also involves complicated mathematical, statistical, and economic issues.

The case study also discusses the special considerations that colon screening programs present to a CEA. These factors include patient characteristics, the type of testing procedures used, the varying accuracy of the different procedures, different ways that cancer can originate, the order and frequency of testing, and a host of other variables that must be included in a thorough evaluation.

To illustrate the evaluation of costs and benefits of screening for colon cancer, the case study evaluates a colon cancer screening program for a 50-year-old, average-risk woman using eight different combinations and frequencies of screening tests. Cost, screening regimen, efficacy data, outcome information, etc., are examined in a sensitivity analysis to determine how the different variables affect the mortality rate and cost of the various screening programs. The analysis compares the decrease in the probability of diagnosis of colon cancer, improved life expectancy, increases in screening costs, and decreases in lost earnings, as a result of different screening strategies.

Prepared by: David M. Eddy. Published in April 1981 as Case Study #3 of *Background Paper #2: Case Studies of Medical Technologies* (19 pp., 32 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 81-209 785.

CASE STUDY #4

Cost Effectiveness of Automated Multichannel Chemistry Analyzers

This case study illustrates the possible techniques for evaluating the costs and cost effectiveness of automated multichannel chemistry analyzers. It also examines and discusses the limitations due to data deficiencies, areas for future research, and influences of clinical practice on the evaluation of such analyzers.

The case study begins with a brief description of the history of the multichannel chemistry technology. Next it presents an analytical framework for evaluating the cost effectiveness of the multichannel analyzer. It also reviews the available data concerning the cost of multichannel chemistry analyzers. Finally, as an illustrative example, it uses the analytic framework to examine the evidence concerning the cost effectiveness of using the cardiac enzymes and isoenzymes in the diagnosis of myocardial infarction (heart attack).

The study discusses several important issues related to the clinical efficacy and cost effectiveness of clinical laboratory chemical tests. A prominent example of such an issue is the potential influences on physicians' test-ordering behavior that may be induced by the availability of multichannel analyzers.

The study suggests that various types of automated multichannel chemistry analyzers could be compared to one another under specified circumstances. For example, continuous-flow multichannel models could be compared to discrete-sample multichannel models (and even single-channel models) to find the most cost-effective method of running specific tests. The case also discusses the possibility of comparing the efficiency of using the automated multichannel chemistry analyzers under varying workloads (i.e., the number of tests performed per unit of time).

The study addresses the adequacy—or inadequacy—of efficacy information, noting that, such information is not plentiful but that studies designed to produce efficacy data are underway. The case discusses alternative ways to use the technology in various forms to produce the greatest degree of efficiency. The case also discusses the variability of benefits resulting from use of automated multichannel chemistry analyzers. Potential benefits are described from a societal perspective and include potential reduced costs from reduced incidence of unnecessary hospitalization resulting from more accurate diagnostic and monitoring testing. Health benefits could be measured in quality-adjusted life years.

Costs are distinguished from charges, and several direct costs are identified, including those for nonlabor (e.g., equipment, service and maintenance, reagents, and consumables) and labor. Fixed, variable, and induced costs are all addressed. The case states that indirect costs have not been adequately studied and may not be extensively affected by automated analyzers. Discounting would be included in analyses described in this case

study, as would the use of sensitivity analysis. The extent to which sensitivity analysis would be used is not explained explicitly.

Data results are not derived from this case study; however, the many different ways a CEA of multichannel chemistry analyzers could be conducted are discussed. Each different approach would yield results of a different meaning; hence several caveats would be needed for each approach and set of results.

The case discusses the potential public policy implications of this analysis which could affect reimbursement policies regarding laboratory tests, the use of automated analyzers by hospitals and physicians, and the design of equipment by manufacturers. No conclusions regarding the cost effectiveness of automated multichannel chemistry analyzers can be drawn from this study. The study was not designed to be an actual assessment; rather, it was intended to illustrate how a CEA of automated analyzers could be performed.

Prepared by: Milton C. Weinstein and Laurie A. Pearlman. Published in April 1981 as Case Study #4 of *Background Paper #2: Case Studies of Medical Technologies* (36 pp., 55 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 81-209 793.

CASE STUDY #5

Periodontal Disease: Assessing the Effectiveness and Costs of the Keyes Technique

This case study examines the effectiveness and costs of the Keyes technique, a nonsurgical method of treating periodontal disease that involves an extensive regimen of oral hygiene and plaque removal measures by the patient, supervision by the dentist, inexpensive and readily available chemicals (e.g., hydrogen peroxide and baking soda), and assessment of bacterial control by regular microscopic examination of material from the periodontal tissues.

The case used data collected in 1979 from 18 dental practices in the Washington, D.C., Standard Metropolitan Statistical Area and involving 190 patients and 800 office visits as the basis for a short-term assessment of the effectiveness of the Keyes technique and an estimate of its costs of delivery. Overall improvement of dental health as measured by five indicators (e.g., bleeding of gums on probing, loose teeth) was shown to be statistically significant in patients using the Keyes technique. The case study stressed, however, that long-term clinical studies of the efficacy and effectiveness of both the Keyes technique and of periodontal surgery are necessary in order for definitive conclusions to be drawn.

The average variable *cost* of producing each visit for the Keyes technique in 1979 was estimated to be between $17.87 and $13.72. The average

reported *charge* for each visit in 1979 was between $31.63 and $27.83. Some dentists charged on the basis of total treatment, and the charge averaged a little over $120. A significant portion of the expenditures for periodontal disease in this country is for periodontal surgery. The case purported that the cost effectiveness of the Keyes technique, if it does have long-term effectiveness, depends in part on the amount of periodontal surgery that is avoided by patients who use it.

Prepared by: Richard M. Scheffler and Sheldon Rovin. Published in May 1981 as Case Study #5 of *Background Paper #2: Case Studies of Medical Technologies*. Includes commentary by: Allan J. Formicola, R. Gottseg, S. Socransky, J. Hay, et al. (32 pp., 13 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 81-221 780.

CASE STUDY #6

The Cost Effectiveness of Bone Marrow Transplantation and Its Policy Implications

This case study is a cost-effectiveness analysis (CEA) of bone marrow transplantation, a highly sophisticated and very costly emerging medical technology used in the treatment of aplastic anemia and acute leukemia. The data on treatment cost and effectiveness (lives saved, years of life saved, and quality-adjusted years of life saved) of bone marrow transplantation were empirically derived from the UCLA Bone Marrow Transplant (BMT) Program. The effectiveness data for patients treated by conventional therapy had been previously published. Quality of life for patients undergoing bone marrow transplantation was evaluated by a BMT Program nurse.

Patients with severe aplastic anemia and patients with leukemia who are unresponsive to conventional therapy are potential candidates for bone marrow transplantation therapy. There were insufficient resources to allow all eligible patients into the BMT Program, so the survival of patients who received transplants is compared to those who would have been selected had a suitable bone marrow donor been available. The sample sizes were very small, and survival data were limited to 3 years as a result of the newness of the technology. For patients undergoing "successful" transplants (defined as those patients still living after 3 years), normal life expectancy is assumed in order to be conservative.

Bone marrow transplant procedures are compared to conventional therapy rather than to no treatment, although there is no evidence that conventional treatment is efficacious. Conventional therapy for aplastic anemia involves corticosteroids, and androgens, and red blood cell and platelet transfusions. Conventional therapy for acute leukemia consists of various combinations of chemotherapy. The cost of bone marrow transplantion is considered to be the incremental—or avoidable—cost above what would have been spent on conventional therapy.

Hospital charges are used as proxies for direct costs (medical costs) of bone marrow transplantation and conventional therapy; indirect costs (lost wages) are calculated only for bone marrow donors and the families of patients receiving transplants.

The results of the analysis are expressed as two cost-effectiveness ratios, one with "lives saved" as the denominator and the other with "years of life extended" as the denominator. A discount rate of 10 percent is applied to future benefits (years of life extended), and rates of 8 and 12 percent are applied to test for sensitivity. All costs are assumed to occur in the present. Efforts are made to adjust for quality of life. The cost-effectiveness ratios developed for bone marrow transplant procedures are compared to those of other life-saving programs, and an extensive discussion on the relevance this study has to public policy is presented. Equity issues were not directly addressed in this study, as bone marrow transplantation is still being employed in a research mode.

Prepared by: Stuart O. Schweitzer and C. C. Scalzi. Published in May 1981 as Case Study #6 of *Background Paper #2: Case Studies of Medical Technologies* (15 pp., 10 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 81-221 798.

CASE STUDY #7

Allocating Costs and Benefits in Disease Prevention Programs: An Application to Cervical Cancer Screening

This case study suggests that one important reason for neglect of disease prevention/health promotion programs is that the benefits accrue primarily in the future to parties other than those who incur the immediate costs. The case also suggests that since the private sector is often expected to fund such programs, cost-effectiveness analyses (CEAs) performed from the societal perspective alone may not be adequate for developing public policy.

To demonstrate the application of a CEA from different perspectives to disease prevention and health promotion programs, this case study presents a CEA of cervical cancer screening. First, the disease process is modeled by using a Markov Chain technique to "age" a simulated population of 30- to 39-year-old women for 10 years (using disease transition probabilities reported in the literature). The cost effectiveness of screening at different intervals—ranging from annual screening to no screening for the 10-year period—is then calculated. The effects of different migration patterns, different risk groups, different modes of administering Pap tests, and joint production considerations are considered. The sensitivity of the results to various discount rates and to the range of error rates for Pap tests is tested.

The results indicate that a private party always has a financial incentive to postpone screening, whereas society finds it more cost effective to screen,

but only at infrequent intervals. In addition, the study notes, the cost effectiveness of screening is markedly affected when a more efficient (i.e., less costly) delivery mode is simulated. Screening is significantly affected when joint production effects are considered. The cost effectiveness of screening, however, is not very sensitive to small changes in the discount rate, initially set at 10 percent, nor to varying assumptions regarding error rates.

The case study concludes that if society wants the private sector to screen for cervical cancer at a socially determined optimal rate, then society must be willing to subsidize the cost of the program. The study also concludes that the cost effectiveness of cervical cancer screening is much more affected by the cost assigned to screening than by different assumptions regarding discount and error rates.

The cost effectiveness of screening at each simulated interval was compared to no screening for a 10-year period. Efficacy information was addressed, and different test error rates were used. The production of the Pap test was simulated, for cost purposes, at two levels: an expensive university hospital clinic using specialists, and an inexpensive health clinic using licensed nurses. Only lives and years of life saved were identified as benefits.

Costs were distinguished from charges, marginal costs were considered, and indirect costs are used. Discounting of costs and benefits was done (rates tested: 0, 5, 8, and 12 percent), and sensitivity analysis was performed; however, issues of equity were not directly considered in the analysis.

Prepared by: Office of Technology Assessment. Published in May 1981 as Case Study #7 of *Background Paper #2: Case Studies of Medical Technologies* (31 pp., 42 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 81-221 806.

CASE STUDY #8

The Cost and Effectiveness of Upper Gastrointestinal Endoscopy

This case study examines the use of the fiberoptic endoscope to visualize the upper gastrointestinal (UGI) tract from the esophagus to the upper portion of the small intestine. This common form of endoscopy is generally performed to document a condition such as the size of a hiatal hernia or the site of a UGI hemorrhage. Issues related to evaluating endoscopy's benefits and costs are discussed, though no formal comparison of costs and benefits is undertaken.

The case study describes the technique of endoscopy and the device used —the fiberoptic endoscope. It briefly touches on training in the technique and identifies the common medical indications for endoscopy's use.

The case study also discusses the clinical effectiveness of UGI endoscopy, which is used to diagnose conditions of the UGI tract and to obtain specimens of tissue. The medical indications for use of the procedure are quite broad and inclusive. Studies of the diagnostic value of the technique suggest that endoscopy significantly contributes to the amount of diagnostic information. Very often, however, the medical condition being diagnosed is such that the information gained does not improve morbidity or mortality for the patient(s).

The case states that the most common dangers associated with endoscopy are perforation (esophagus or stomach), bleeding, cardiopulmonary effects, and infection. These complications are relatively rare, yet not insignificant given the large number of endoscopies performed nationally (at least 500,000 each year).

The case distinguishes between the cost of performing endoscopy and the charges for it. Data from California indicate a median charge in 1977 of approximately $240, and by extrapolation, a total national expenditure of $122 million. A hypothetical cost analysis, however, estimates that the average cost to a physician for performing a routine endoscopy ranges from $41 to $83.

The study addresses issues in evaluating benefits and costs of endoscopies. The case points out the difficulties of adequately evaluating the benefits of a diagnostic procedure such as endoscopy. There are very few data in the literature to substantiate a claim that UGI endoscopy leads either to better patient outcome or reduced use of similar technologies. Documenting the value of this technology would take expensive, time-consuming randomized clinical trials. In an era of increased competition for resources, the case study suggests, trials of a procedure with such low morbidity and relatively low individual costs are unlikely to be funded. Additional problems include the difficulty of conducting a clinical trial ethically when life-threatening conditions such as gastric cancer are involved and problems in extrapolating from the results of clinical trials. The case study states that because of these difficulties in assessing benefits, cost-effectiveness and cost-benefit studies would be limited in usefulness. Though theoretically possible,

measurements of costs and benefits are unlikely, since such measures cannot realistically be made sensitive enough to provide an accurate and useful assessment for decisionmakers.

The case also discusses policy considerations pertaining to the use of endoscopy, including financial and other incentives that encourage the use of the procedure. Finally, the need for increased investigation of more narrowly defined indications for use of endoscopy is discussed.

Prepared by: Jonathan A. Showstack and Steven A. Schroeder. Published in May 1981 as Case Study #8 of *Background Paper #2: Case Studies of Medical Technologies*. Includes Commentary by the American Society for Gastrointestinal Endoscopy (21 pp., 47 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).
Available from: National Technical Information Service, order #PB 81-221 814.

CASE STUDY #9

The Artificial Heart: Costs, Risks, and Benefits

This case study reviews the potential benefits, costs, and risks of the artificial heart, as well as the technological problems that remain to be solved.

Cardiac disease kills over 800,000 persons yearly. The number of people that might benefit from total heart replacement would depend on the severity of concomitant illness, age restrictions, access to emergency coronary care, and the nature of the artificial heart itself. Assuming that in order to be a candidate for heart replacement, a person must be in the hospital, with death imminent or highly probable, that the patient's circulation can be supported long enough for transportation to an institution with appropriate facilites, that the patient does not suffer from serious or chronic noncardiac disease, and that he or she is under 65 years of age, the case study estimates that there would be 33,600 candidates each year. A low estimate of 16,000 candidates would result if large or intractable technical problems were encountered or if some patients chose not to accept the device, and a high estimate of 66,000 candidates would result if patient selection criteria were relaxed.

The case study calculates that the availability of an artificial heart may extend the lives of individuals who suffer from cardiac disease, on the average, by 0.6 of a year (about 210 days). It might extend the life of a randomly chosen 25-year-old member of the population, on the average, by about 0.0966 of a year (about 35 days). An optimistic estimate is that 60 percent of artificial heart recipients employed prior to implantation would return to work.

As the artificial heart becomes available, the case study suggests, it will be nearly impossible to deny the demand for its widespread use, as the recent history of hemodialysis demonstrates. Even the minimum estimates of the cost for an individual to receive an artificial heart involve an amount that would be a severe burden on most families. The case study presents

estimates for the cost of artificial heart implantation (device plus hospital and physicians care) ranging from $24,000 to $75,000 per patient. It also presents cost estimates for continuing medical and technological care ranging from $1,800 to $8,800 per patient per year. Since insurance companies will probably be unwilling to cover the high costs of this treatment without special premiums or other incentives, the case study suggests, the Federal Government will be faced with a serious dilemma: to allow those who cannot afford to pay privately to do without a lifesaving device, or to devote up to an additional $1 billion to $3 billion annually to this new medical technology. A decision to finance the artificial heart with Federal funds must take into account potential loss of other social programs displaced by the development of the artificial heart. The artificial heart may proportionately raise social expenditures financed through medicare and social security that will have to come from other social programs.

Artificial heart research represents the first prototype of a comprehensive program to develop a concrete medical device. Although this research has led to useful therapeutic inventions and substantial advances in understanding, the case study indicates, the development of a clinically acceptable implantable artificial heart seems unlikely in the near future. As yet, neither a hemocompatible material nor a portable power source that can meet the specifications for a long-term, implantable heart in laboratory testing has been developed. Current prototypes of 2- and 5-year left-ventricular assist devices use electrical battery systems that still have mechanical and operational liabilities.

From the perspective of a member of society, the case study observes, investment in artificial heart devices may be no closer to saving his or her life and health than a comprehensive, effective cardiac disease prevention program. This fact gives society considerable leeway in how it chooses to attack the massive costs of heart disease in our society. For this reason, society should compare the benefits and costs of the artificial heart with those of other social and medical programs designed to extend life and improve its quality.

The case study notes that there are two major issues involving the development of the artificial heart which must be resolved before it will be possible to comprehend fully the device's total impact. First, the Federal Government must decide whether it is willing and has the capability to ensure equitable access to the device—assuming this responsibility may substantially increase the perceived cost of the program. Second, the acceptance or rejection of a nuclear power source should be made explicit—the nuclear heart device may substantially enhance the attractiveness of the device from a clinical standpoint but will also involve very large social costs and risks.

Prepared by: Deborah P. Lubeck and John P. Bunker. Published in May 1982 as Case Study #9 of *Background Paper #2: Case Studies of Medical Technologies* (94 pp., 78 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

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CASE STUDY #10

The Costs and Effectiveness of Neonatal Intensive Care

This case study reviews the literature on the efficacy and effectiveness as well as the utilization and cost of neonatal intensive care. The widespread application of neonatal intensive care, it notes, appears to have played a major part in producing the improved survival, as well as the improved physical condition, of very low birthweight infants in recent years. The need for intensive medical care of high-risk newborns is likely to increase over the next decade because of rising birth rates and the high level of risk factors associated with low birthweight (e.g., teenage pregnancy and low socioeconomic status).

One of the problems in evaluating neonatal intensive care services, the case study notes, is the absence of uniform definitions. Technological or personnel capabilities vary considerably in different hospitals, and the organization of neonatal services in many hospitals does not reflect the three levels of care defined by the Committee on Perinatal Health. Furthermore, regulatory and reimbursement policies create incentives for hospitals to classify their neonatal intensive care units (NICUs) inappropriately. The absence of uniform definitions of levels of neonatal intensive care has complicated data collection, making statistical analysis difficult.

The case study examines factors that influence the present and future need and demand for neonatal intensive care services in the United States: birthweight, prematurity, race, socioeconomic status, birth rate, congenital anomalies, maternal age, prenatal care, and medical practices. The main determinants of the future demand for newborn intensive care, the case study indicates, will most likely be the duration of the current baby boom and the rates of prematurity and low birthweight. Since 1966, the incidence of low birthweight infants as a proportion of all births has decreased; however, the U.S. birth rate has increased nearly 7 percent since 1975, and this has increased the absolute number of very low birthweight infants born each year since 1974. Continued increases in the number of very low birthweight infants will expand the need for neonatal intensive care services.

The case study gives rough estimates for the current utilization of neonatal intensive care in the United States. Since there are no national data available, estimates concerning NICU admission rates (6 percent of live births), length of stay (8 to 18 days per patient), total days of care (2.6 million), and the number of intensive care beds (7,500 beds) are extrapolated from data in the literature and from individual NICUs.

Next, the case examines the costs of neonatal intensive care, by birthweight, diagnosis, and outcome. Cost data, the case study notes, are plagued by even more limitations than utilization data. Nevertheless, available studies do show that total costs for survivors are higher than for nonsurvivors; as birthweight decreases, cost increases; and total costs increase with complications such as hyaline membrane disease. Current reimbursement for neonatal intensive care (e.g., by a uniform per diem rate), the case study

indicates, encourages cross-subsidies, so that costs properly attributable to one patient may be borne by other patients. The case study estimates average expenditures per patient in 1978 to be about $8,000, with reports in the literature ranging from $1,800 to $40,000 per patient. For the United States as a whole, the cost in 1978 is estimated to be about $1.5 billion.

The case also reviews the literature on the effectiveness of neonatal intensive care. Outcomes are defined in terms of improved mortality and morbidity rates. The fact that mortality rates within birthweight groups have declined over time, the case study suggests, strongly supports the conclusion that neonatal intensive care has helped improved survival. With respect to morbidity, the case study finds that the incidence of serious problems in survivors of neonatal intensive care is probably decreasing; however, the absolute number of severely handicapped survivors, especially among infants weighing 1,000 g or less at birth, is increasing.

The information needed for a comprehensive cost-effectiveness analysis or cost-benefit analysis (CEA or CBA), the case study indicates, is not currently available. Thus, in order to discuss the findings cited above in an economic framework, the case uses a method of economic analysis (a hybrid CEA/CBA) to compare neonatal intensive care with less intensive care of small or ill newborns. Neonatal intensive care of the subgroup of infants weighing 1,000 g or less does not turn out to be cost effective, mainly because the small increase in the chance that a severely abnormal individual in this birthweight group would survive outweighed, in economic terms, the fact that the odds of a normal survivor in this group increased from 17 per 1,000 live births to 135 per 1,000 live births between 1960 and 1970-75. Withholding care from all newborns weighing 1,000 g or less to avert the exceptional costs of the severely abnormal survivors would take the lives of many potentially normal babies. Clearly, the case study indicates, "a decision to withhold care from such infants would not be made on cost-effectiveness considerations alone." Furthermore, the case study notes, blacks have a far greater proportion of very low birthweight infants who are saved by intensive care, so substantial reductions in access to such services would have a disproportionately adverse effect on the survival of black newborns.

The last section of the case study suggests revisions in Federal policies to reflect the changes that have occurred in neonatal intensive care. Revisions in both the neonatal resources standards in the National Guidelines for Health Planning and in the Medicaid and Social Security provisions for reimbursement of neonatal care costs are proposed.

Prepared by: Peter Budetti, Peggy McManus, Nancy Barrand, and Lu Ann Heinen. Published in August 1981 as Case Study #10 of *Background Paper #2: Case Studies of Medical Technologies* (51 pp., 136 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 82-101 411.

CASE STUDY #11

Benefit and Cost Analysis of Medical Interventions: The Case of Cimetidine and Peptic Ulcer Disease

This case study has two major goals: 1) to assess the available evidence regarding the benefits and costs of cimetidine in the treatment of peptic ulcer disease, and 2) to explicate a useful cost-benefit model for evaluation of medical technology. The study approaches these objectives by applying the model to the evaluation of cimetidine and ulcer disease. The analysis in the case is organized in three parts: 1) a development and discussion of a general cost-benefit model for medical interventions, 2) an overview of peptic ulcer disease in the United States, and 3) a discussion of the development, diffusion, and use of cimetidine.

The cost-benefit model distinguishes two principal classes of effects—clinical effects and health system effects. The specific components of these effects depend on the population and intervention being examined, and any evaluative model should apply to an identifiable patient population and specific health care interventions. The patient population may be defined in terms of a diagnostic category, clinical signs or symptoms, risk factors, or complications of disease. Clinical and health system effects interact to lead to an outcome in terms health status and resource costs.

The case critically reviews a host of studies dealing with the safety, efficacy, and effectiveness of cimetidine. Among the short-term clinical effects assessed are healing, pain relief, safety, adherence to the treatment plan, complications, and recurrence. The case also reviews recommendations for treating newly diagnosed, uncomplicated ulcers. The principal long-term clinical effects examined are recurrence and safety, and the Food and Drug Administration's approval of cimetidine for long-term use is discussed.

The case examines the effects of cimetidine use on the health system and outcome in terms of health and of resource costs. Among the variables evaluated are medication, diagnostic tests, physician visits, mortality, morbidity, and resource costs. These three areas—clinical effects, health system effects, and outcomes of cimetidine use—are the primary elements of the cost-benefit analysis that is performed.

The case states that the literature supports the following findings, among others: compared to placebo, cimetidine promotes healing and provides faster and more complete pain relief for duodenal ulcers; it may be more effective than placebos for patients with gastric ulcers; when used for up to 2 months, cimetidine appears to be a relatively safe drug; most known side effects are minor or reversible; cimetidine plus moderate amounts of antacid costs no more than a therapeutically equivalent course of intense antacid therapy; and maintenance treatment with cimetidine for as long as a year significantly reduces the chance of ulcer recurrence (compared to a placebo) during the period of treatment. Cimetidine also appears to have contributed to a sharp decline in surgery for ulcer disease in 1978, and may allow patients to lose significantly fewer days of work than patients given a placebo.

These findings and conclusions indicate that cimetidine, when used for the treatment of peptic ulcer disease, provides a substantial benefit to cost ratio to the peptic ulcer patient and the health care system. The case cites the findings of two other studies: one by the Netherlands Economic Institute in 1977 and the other by Robinson Associates, Inc., in 1978. An in-depth review and critique of the Robinson study is included.

Prepared by: Harvey V. Fineberg and Laurie A. Pearlman. Published in September 1981 as Case Study #11 of *Background Paper #2: Case Studies of Medical Technologies* (64 pp., 157 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 82-118 910.

CASE STUDY #12

Assessing Selected Respiratory Therapy Modalities: Trends and Relative Costs in the Washington, D.C. Area

This case study is basically a cost analysis of alternative methods to deliver respiratory therapy. The case describes the technology of respiratory therapy, the indications for the use of each type of therapy, and the substitutability of different modalities. The case also reviews the literature on effectiveness and concludes that respiratory therapy's efficacy and effectiveness has not been adequately proved and is still in dispute.

The case describes an empirical survey which the authors undertook in the metropolitan Washington, D.C., area. Using data from that survey, the case charts the utilization of respiratory therapy techniques by type of hospital and by number of beds. It also charts the trends in use from 1976 to 1979, noting a shift from the more expensive high-technology oriented therapy intermittent positive pressure breathing, better known as IPPB, to the less expensive simpler aerosols and spirometers.

In the cost analysis, the case compares specific types of respiratory therapy with another. Cost savings of the shift in technology are estimated. By focusing on a cost-comparison analysis, the case implicitly assumes that efficacy and effectiveness across therapies are constant. The costs of one therapy are compared with those of the others.

The adequacy of efficacy and effectiveness information is addressed (and found to be inadequate). Effectiveness and specific benefits are not identified, measured, or valued. Costs are distinguished from charges, and "avoidable," or incremental costs are identified. The indirect costs (lost production) are not identified. Discounting is not used (costs are incurred in the present, future benefits are not projected). Sensitivity analysis is not used, and issues of equity are not addressed. Public policy considerations are discussed.

Prepared by: Richard M. Scheffler and Morgan Delaney. Published in July 1981 as Case Study #12 of *Background Paper #2: Case Studies of Medical Technologies* (23 pp., 38 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 82-101 122.

CASE STUDY #13

Cardiac Radionuclide Imaging and Cost Effectiveness

This case study examines a wide range of issues that deal with the recent growth and expanded use of cardiac radionuclide imaging technology in the health care field. The areas addressed are the present and potential future characteristics of the technology; the market for and industry involvement in cardiac imaging; the uses and users of these procedures; the clinical efficacy and risks associated with the techniques; the costs and charges of imaging technology use; and the cost effectiveness of these procedures.

The case points out that much of the rapid diffusion of cardiac nationwide imaging is taking place without full understanding of the benefits and limitations of the techniques. To date, only very selected patient populations have been evaluated; extrapolation of results to other populations remains to be demonstrated. Adding to the uncertainty are the concurrent technological changes that are taking place.

Using suggested clinical indications for the use of cardiac imaging, the case study estimates that the potential target population could range from 11.7 million people per year (if scans were restricted to people with suspected or established coronary heart disease) to 70.8 million people per year (if routine screening were applied to all persons 40 years of age and over).

To estimate the financial costs of cardiac imaging services, the case examines direct nonlabor costs (equipment, maintenance, radionuclides, etc.), direct labor costs (personnel needs, training, support staff), and indirect costs (overhead). It estimates that the average annual fixed costs of an operating radionuclide laboratory are about $113,800 (1980 dollars) and that the resource costs of the various imaging procedures range from $73 for "hotspot" studies with technetium 99m to $258 for thallium exercise-redistribution studies. Significant variations appear to exist across the country in the charges rendered for the various procedures.

The case examines extant studies (up to 1980) to determine the clinical efficacy of cardiac imaging procedures and the potential value of the diagnostic information obtained in facilitating the diagnosis of coronary artery disease, and understanding the extent of the disease or its response to treatment. Imaging procedures are well documented to be both more sensitive and more specific than exercise stress tests. The maximum information value appears to be obtained in patients with symptoms suggestive of coronary artery disease in whom the diagnosis is uncertain.

Limited cost-effectiveness analysis of diagnostic strategies involving cardiac imaging procedures concludes that "decision strategies based on threshold cutoff probabilities of disease are more cost-effective than blanket testing of a population . . . and that use of cardiac imaging appears to identify additional surgical candidates at reasonable cost when compared to exercise stress testing." The reasonableness of these additional costs will depend, to a large extent, on the incremental health benefits achieved by coronary artery bypass surgery.

Finally, the case identifies (but does not attempt to address) some of the policy issues raised by this emerging technology. Among these are issues of reimbursement, safety and efficacy, disposal of the radionuclide wastes, clinical standards and indications for use, and responsibility for controlling the diffusion of the technology throughout the medical community.

Prepared by: William B. Stason and Eric Fortess. Published in May 1982 as Case Study #13 of *Background Paper #2: Case Studies of Medical Technologies* (59 pp., 88 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 82-239 989.

CASE STUDY #14

Cost-Benefit/Cost-Effectiveness of Medical Technologies: A Case Study of Orthopedic Joint Implants

This case study examines the feasibility and potential usefulness of undertaking cost-effectiveness analysis/cost-benefit analysis (CEA/CBA) of orthopedic joint prostheses. Two specific issues are addressed: 1) whether it is feasible to evaluate carefully and completely the orthopedic joint implant technology within a CEA/CBA framework, and 2) how such an evaluation could be useful in formulating public policy.

The case presents a state-of-the-art study of CEA/CBA as it pertains to this technology. The study includes a description of joint implants based on a review of the literature, communications with selected medical specialists, and conversations with representatives of the orthopedic prostheses industry. The case briefly discusses alternative forms of treatment for arthritis and points out an important difference between the alternatives (e.g., drugs) and joint implants: most alternatives are only short-run measures, whereas joint implantation is a long-term measure.

The case notes that few data are available regarding the efficacy of joint implants. Data regarding the efficacy of hip replacements are better than the data for other joint implants or alternative measures and may even be acceptable. Efficacy studies are in progress for some implants.

Potential benefits of joint implants are put into two categories: direct and indirect. Potential direct benefits discussed include relief of pain, improved functional status of joint, measures included in the "Sickness Impact Profile" (e.g., social interactions, ambulation, sleep, leisure, and emotions), quality-adjusted life years (QALYs), and earnings. Potential indirect benefits include averted expenditures for the caring for, and treatment of, individuals handicapped with debilitated joints (e.g., those with severe arthritis).

Some indirect costs, including loss of productivity when a patient is hospitalized, are identified. The case points out that both indirect and direct costs of complications associated with joint implants must be considered as well as the costs of followup care and rehabilitation therapy.

Prepared by: Judith D. Bentkover and Philip G. Drew. Published in September 1981 as Case Study #14 of *Background Paper #2: Case Studies of Medical Technologies* (19 pp., 72 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).
Available from: National Technical Information Service, order #PB 82-120 833.

CASE STUDY #15

Elective Hysterectomy: Costs, Risks, and Benefits

This case study examines elective hysterectomy as it is used for sterilization and cancer prevention. The focus of the study is a review of the literature and the issues surrounding the costs, risks, and benefits of elective hysterectomy. The study does not attempt to establish the cost effectiveness of hysterectomy. It does examine the significant side effects of hysterectomy, such as changes in medical utilization and psychological effects following surgery.

The case reviews selected studies that evaluate the efficiency and cost effectiveness of elective hysterectomies. Not taking a cost-benefit approach, these studies do not attempt to value the saving of lives in monetary terms. The first two efficiency studies the case study reviews contrast the direct costs of hysterectomy with the net lifetime costs of gynecological care. Future costs are discounted at rates varying from 3 to 6.5 percent. Another study the case reviews examines the use of hysterectomy as a sterilization device versus the direct costs of tubal ligation plus the expense of future gynecological care which would have been averted by hysterectomy.

The effectiveness of hysterectomies in preventing pregnancy and cancer is not an issue, but the health risks of the procedure are. Efficacy/effectiveness of alternative means to accomplish these objectives are assessed, but not in the cost-effectiveness studies reviewed. Additionally, the cost-effectiveness studies reviewed do not attempt to identify, measure, or place a value on the side effects of surgery.

Costs are distinguished from charges and issues of equity are discussed. The case does not employ a sensitivity analysis. Conclusions are drawn with respect to the cost effectiveness of elective hysterectomies as they are used for the separate purposes that are examined.

Prepared by: Carol Korenbrot, Ann B. Flood, Michael Higgins, Noralou Roos, and John P. Bunker. Published in October 1981 as Case Study #15 of *Background Paper #2: Case Studies of Medical Technologies* (33 pp., 86 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).
Available from: National Technical Information Service, order #PB 82-122 326.

CASE STUDY #16

The Costs and Effectiveness of Nurse Practitioners

This case study reviews the literature on the use of nurse practitioners (NPs) to provide medical services traditionally provided by physicians. Only limited data are available, and much of the available information deals with other types of nonphysician health professionals. In addition, from the perspective of cost-effectiveness analysis, the most serious problem is the lack of specific definition of the medical care tasks NPs are qualified to perform and actually perform in different settings.

Although the case study makes no attempt to develop cost-effectiveness ratios, it does elaborate on the factors essential to determining the cost effectiveness of NPs. These include the specific services NPs are qualified to provide, performance quality, productivity, task delegation experience, changes in physician practice subsequent to the introduction of NPs, employment costs, impact on average expenses per patient visit, training costs, and revenue generation ability. From the data that do exist, it appears that NPs offer the potential to reduce the cost of health care and improve access to the health care system.

A key question examined by this study deals with the nature of the services NPs perform and how they affect costs. In general, NPs provide complementary and substitute services. Complementary services would include care such as patient counseling, while substitutive services refer to those commonly provided by physicians, such as well-baby examinations. Because data on services provided are often reported in terms of office visits rather than specific tasks, it is not possible to compare the nature of the services provided by an NP and a physician, even if they are recorded under the same classification (e.g., well-baby office visit).

In terms of quality of care, NPs appear to provide care that is of as high quality as that of physicians (with whom they usually work and are compared). There is some evidence that NPs working according to protocols may provide services of even better quality than those provided by some physicians. Productivity is more difficult to assess and depends on how NPs are used. There seems to be clear evidence that the use of NPs improves physicians' productivity, but it is not clear how this improved productivity affects costs.

Analysis of the cost effectiveness of NPs must consider both the amount of time spent by them to perform a given service and the cost per unit of time. NPs tend to spend more time per patient and log more patients visits per time period. In addition to the costs of salary, fringe benefits, and physician supervision, there may be costs associated with the need for increased staff support, space, equipment, and certain NP practice patterns (e.g., NPs may perform more diagnostic tests than do physicians). When all cost factors have been considered, however, studies have found NPs to perform comparable medical tasks at a lower total cost than physicians. Whether this translates into lower expenses per patient visit depends on total practice expenses and patient volume. Moreover, studies indicate that lower costs

associated with NPs do not necessarily translate into lower prices for their services.

The study concludes that given current employment and pricing patterns, NPs do marginally increase medical care expenditures beyond what would have occurred without them. It has been documented that individual NPs can be cost effective. Generalizing that experience to the total NP population or basing future policies on those individual experiences alone are much more problematic given the multiple practice and policy factors that currently affect their roles.

Prepared by: Lauren LeRoy and Sharon Solkowitz. Published in July 1981 as Case Study #16 of *Background Paper #2: Case Studies of Medical Technologies* (37 pp., 110 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

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CASE STUDY #17

Surgery for Breast Cancer

This case study is an examination of the scientific and technical issues that are part of the debate over the appropriate approach to detecting and treating breast cancer. A major focus of the analysis is a review and discussion of the role played by individuals of the medical profession in the diffusion or acceptance of different therapies. The study includes a review of the various types of diagnostic tests surgical and nonsurgical tests used to treat breast cancer. The case notes that the resolution of the detection and treatment issues will have major cost and benefit implications. The case also performs a hospital cost analysis of two different treatment strategies—inpatient versus outpatient tissue biopsy.

The background of the case study is established by a brief overview of the extent and effects of breast cancer in America. A history of cancer of the breast is presented, as is a description of the development and popularization of the Halsted method of performing radical mastectomy procedures to treat breast cancer. Developed in the late 1880s, the Halsted method remained the generally accepted "treatment of choice" for over 80 years—in 1970, 80 percent of breast cancer patients in the United States received radical mastectomies.

Variations of the Halsted method and completely new approaches to treating breast cancer (both surgically and nonsurgically or a combination of both techniques) over the last two decades have challenged the traditional Halsted technique. The case examines the evidence regarding the efficacy, safety, mortality, and morbidity of these new techniques, as well as that for the Halsted method.

The six treatment procedures they examine are: 1) radical mastectomy, 2) extended radical mastectomy, 3) modified radical mastectomy, 4) simple or total mastectomy, 5) partial mastectomy, and 6) local excision, lumpec-

tomy (or tylectomy). Special emphasis is placed on reviewing the status of the nontraditional methods of treating breast cancer, i.e., those procedures that run contrary to the Halsted approach (radical mastectomy).

Prominently discussed are the roles of three American surgeons—Dr. Leslie Wise, Dr. George Crile, Jr., and Dr. Oliver Cope—who have long advocated and practiced a more limited surgical approach to treating breast cancer. It describes the reason they came to advocate on alternative treatment and the varying degrees of success they have had in changing the behavior of their surgical colleagues within their hospitals.

The case summarizes the debate by discussing the results of the National Cancer Institute's consensus panel meeting on the topic of breast cancer treatment held June 5, 1979, at the National Institutes of Health. In essence, the conclusion was that much work is left to be done in evaluating the various techniques. The conference recognized the potential of the nontraditional procedures and the value of the total mastectomy as used in place of the Halsted radical procedure for certain women. More information is needed regarding the efficacy and safety of the alternative procedures; segmental mastectomy, primary radiotherapy, etc. Over the last few years, the modified radical procedure has become more popular than the Halsted radical technique, but there is still no general consensus on what procedure(s) should be the treatment of choice.

The case indicates that there is good evidence that survival rates are no better for the radical procedures than for the less severe techniques available. Why then is there still adherence to the more drastic approach? The case sets out a number of micro and macro issues that may help explain the continued reliance on the Halsted method: cultural and traditional reasons, economic incentives, individual personalities and reputations, existing logic of cancer treatment, structure of the medical specialties, burden of proof requirements on innovators and traditionalists, medical conservatism, and criteria for weighing the evidence.

The cost analysis, as mentioned above, is a comparison of the cost differences of inpatient versus outpatient tissue biopsy. The case considers these alternative strategies in light of the number of cases of breast surgery at Massachusetts General Hospital in 1976 and the total number of procedures for the United States in 1975. The calculations and extrapolations determined that $185 million (excluding radiation therapy) or a 45-percent reduction in total costs would result per year if outpatient biopsies were used uniformly and radical surgery were replaced with more limited surgery. However, as the case notes, the reader must realize the very approximate nature of cost analysis. Nevertheless, the magnitude of the cost differences warrants a more complete investigation.

Prepared by: Karen Schachter Weingrod and Duncan Neuhauser. Published in October 1981 as Case Study #17 of *Background Paper #2: Case Studies of Medical Technologies* (29 pp., 55 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

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CASE STUDY #18

The Efficacy and Cost Effectiveness of Psychotherapy

This case study describes a variety of methodological and substantive problems that arise in assessing the effects of mental health treatments. The report both summarizes the existing literature and attempts to present the divergent perspectives within the research-policy community concerned with psychotherapy. As described below, it deals with four issues that are centrally related to the evaluation of psychotherapy.

Definition—Psychotherapy is not a simple intervention, and part of the confusion about its effectiveness has to do with reviewers' use of different definitions. The case study uses a relatively broad definition of psychotherapy in order to best represent current therapy practice. This definition includes treatments based on Freudian ideas about psychodynamics, as well as newer therapies based on theories of learning and cognition. The case also notes that psychotherapies are not distinguishable only by their theoretical bases. In addition, patient variables (e.g., intelligence), therapist variables (e.g., empathy), and the nature of the treatment setting affect the nature of psychotherapy. Although the inclusion of such factors makes the analysis of psychotherapy more difficult, there seems to be ample evidence as to the importance of these factors on the outcome.

Assessability—Although psychotherapy itself is complex and there is no clearly agreed upon way of viewing it, the methods for assessing psychotherapy seem better established. The case describes the variety of experimental and quasi-experimental designs that have been used in assessing psychotherapy, along with an analysis of what types of information can be obtained by application of these techniques. The case also describes and analyzes various methodological strategies for measuring the outcomes of psychotherapeutic treatment and the ways in which the reliability and validity of measures are established. Unfortunately, research practice does not always meet these standards. Some explanations offered in the report include the difficulties of withholding treatment and the problems of assessing effects over time. The case also considers the recent development of systematic procedures for synthesizing the findings of multiple investigations. The problems of such techniques, as well as their promise for detecting valid trends in the research literature, are analyzed.

Efficacy—The case describes some of the plethora of research which has been conducted on psychotherapy. The focus of the case's efficacy analysis is a discussion of six important earlier reviews of the psychotherapy literature. In addition, many of the evaluative studies themselves were reviewed. Despite some fundamental differences, both in the criteria they develop for assessing psychotherapy and the studies they include for review, the reviews all seem to support the findings that (under specified conditions) there is evidence as to psychotherapy's effectiveness. In fact, with the exception of reviews that focus on psychoanalytically oriented therapies, there seems to be little negative evidence as to efficacy of such treatments.

Although it is difficult to make global statements, the evidence seems more supportive of psychotherapy than of any alternative hypothesis (spontaneous remission, placebo effects). However, there is a great need for well-conducted research which evaluates psychotherapy for specific disorders under specified treatment conditions. This research would need to be carried out in actual delivery settings.

Cost Effectiveness—The application of cost-effectiveness analysis/cost-benefit analysis of (CEA/CBA) to psychotherapy is much more recent, and hence less developed than efficacy research. Nevertheless, a number of models are available for conducting such analyses. In general, the models are based on those used in other applications of CEA/CBA, and the problems engendered by their use are similar. A particular concern with such psychotherapy assessments is whether costs and benefits can be comprehensively measured. Thus, for example, although the cost of psychotherapy treatment is relatively easy to measure, it is more difficult to determine and quantify what type of benefit has been achieved. Much of the CEA/CBA research to date has involved a comparison of psychotherapy treatments. Although such research indicates the potential use of CEA/CBA to improve the functioning of clinical settings where psychotherapy is given, its use for policymaking is less clear. Such work seems possible, however, and may potentially be incorporated as part of large-scale efficacy assessments.

Prepared by: Leonard Saxe, in part based on a paper prepared for OTA by Brian Yates and Frederick Newman. Published in October 1980 as *Background Paper #3: The Efficacy and Cost Effectiveness of Psychotherapy* (93 pp., 310 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

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CASE STUDY #19

Assessment of Four Common X-Ray Procedures: Problems and Prospects for Economic Evaluation

This case study is about the economic evaluation of diagnostic procedures. The issue of economic evaluation is explored in the context of four X-ray procedures: chest X-ray, skull X-ray, barium enema, and excretory urogram.

First, the case summarizes and reviews five approaches to the evaluation of X-ray procedures used in the literature. Each of these models has a different evaluative endpoint. Studies of diagnostic efficiency measure how often an X-ray procedure gives the correct diagnosis. Studies of diagnostic efficiency examine the frequency with which an X-ray procedure yields positive or abnormal findings under specific conditions of use. Studies of high-yield criteria identify the conditions, symptoms, or risk factors, that justify the use of a procedure. Studies of diagnostic information measure the subjective probabilities of a physician's diagnosis before the test is given against these probabilities after the test. Little change between the prob-

abilities is often interpreted as meaning the test is unjustified. Finally, outcome studies research the implications of test findings for patient outcome. In addition to laying out the strengths and weaknesses of these evaluative models, the case study identifies the conditions under which these models are likely to provide information that can affect patterns of medical care.

The second part of the case study summarizes what is known about the utilization, costs, risks, and benefits of each of the four X-ray procedures, emphasizing the methods employed. The risks are noted and benefits discussed, but discussion of costs is usually missing because of the lack of studies.

The evaluative literature the case study reviews is not comprehensive but includes only those studies that provide information pertaining to at least one of the following questions. Under what conditions, if any, should a procedure be performed? And, how should the procedure be performed? Further qualifications were the existence of specific measures of benefit, cost, or risk; comparison of at least two alternative diagnostic strategies; and analysis of sufficiently large sample to allow meaningful inferences.

The evaluation studies reviewed fall into three categories: the value of a procedure as a screening device, the value of a procedure as a diagnostic test, and the comparison of radiological methods employed. Some of the literature's claims of misuse of the procedures may be valid, while others may be discounted because of study flaws.

Evaluative studies were found to be more frequent for X-ray procedures used for screening than for diagnostic purposes, but in both cases, the studies' influence on medical practice is usually limited. This limited influence is partly due to the flaws in the studies which make their results untrustworthy. A major problem is patient selection bias due to use of uncontrolled study designs. In addition, the implications of diagnostic X-ray results for patient health and well-being and for medical costs are unknown. A more fundamental barrier to the use of evaluations lies in the conflict between the individual patient's benefit and the costs to society.

Because most of the literature does not use cost-effectiveness analyses (CEAs) or cost-benefit analyses and because there is little literature evaluating the subject from an economical stand point, the case does not offer conclusions or policy options concerning the use of this technology. Its point is that until such diagnostic X-ray procedures are evaluated from an economic viewpoint through well-designed studies, the influence of CEA on the use of this technology will be slight, and competent decisionmaking thereby made difficult.

Prepared by: Judith L. Wagner and Martha Krieger. Based in part on a paper prepared for OTA by David Collier. Published in April 1982 as *Background Paper #5: Assessment of Four Common X-Ray Procedures* (62 pp., 126 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology* (Washington, D.C.: U.S. Government Printing Office, August 1980).

Available from: National Technical Information Service, order #PB 83-165 506.

CASE STUDY #20

Mandatory Passive Restraint Systems in Automobiles: Issues and Evidence

In the coldest of analytical perspectives, the purely economic costs of preventing disabilities can be compared with the purely economic costs of dealing with preventable disabilities after they are realized. But the challenge of social resource allocation decisionmaking calls for a more complex and somewhat "warmer" cost-benefit calculus, one that blends economic with humanitarian concerns. In the effort to minimize the adverse consequences of disabilities, analysts must develop measures (or at least concepts) of social cost that incorporate both pecuniary and nonpecuniary costs, which add the costs of suffering to the costs of materials.

The purpose of this case study was not to develop such a social cost-benefit calculus, nor even to array the attributes of alternative disability prevention and treatment technologies in a comparative framework. Rather, it was to introduce the prevention perspective to OTA's study of technology and handicapped people through a study of a single prevention technology, passive restraints in automobiles.

The case study examines issues in the debate on whether passive restraint systems—air bags and automatic belts—should be required in all new automobiles sold in the United States.

Motor vehicle accidents annually kill more than 50,000 Americans (over half of them frontseat occupants of vehicles) and inflict disabling injuries (ranging from temporary and minor to permanent and serious) on an additional 2 million people. Automobile accidents are the leading cause of death and accident-produced disabilities among young people. Some analysts have estimated that passive restraint systems could prevent up to half of the deaths of frontseat occupants and over 100,000 moderate to critical injuries each year.

The case study examines the nature and extent of the automobile safety problem, including accident, death, and injury data, and reviews the record of automobile safety standards and devices, including the current ("active") seatbelt system. It briefly discusses approaches to improving the use of passenger restraints by means other than mandating passive restraints. It then describes the two passive restraint systems—air bags and automatic belts and presents data on their estimated costs, safety, and effectiveness in reducing deaths and disabilities. The case study reviews and compares cost-benefit analyses of these systems, and identifies and discusses the philosophical and ethical issues related to mandating passive restraint systems.

Prepared by: Kenneth E. Warner. Published in September 1982 as *Background Paper #1: Mandatory Passive Restraint Systems in Automobiles: Issues and Evidence* (50 pp., 52 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *Technology and Handicapped People* (Washington, D.C.: U.S. Government Printing Office, May 1982).

Available from: National Technical Information Service, order #PB 83-159 822.

CASE STUDY #21

Selected Telecommunications Devices for Hearing-Impaired Persons

Telephone communication has been, for nearly 100 years, a most pervasive and essential mode of communication interchange among people. But an estimated 440,000 profoundly hearing-impaired persons had, up to 1968, been excluded from telephone use except through third parties.

This case study discusses the introduction and development of telecommunications devices and other technological aids for hearing-impaired people. The 1963 invention by a deaf engineer of a workable coupler interfacing voice telephones and teletypewriters (TTYs) sparked 20 years of development. Using a 5-level Baudot code, chosen because of the availability of equipment programed for its use or compatible with it, the sending coupler, or modem, converts typed information into tones of differing frequency which are compatible with the voice band of the telephone line. These are decoded by a receiving modem and typed out by the receiving TTY.

In 1968, when surplus TTYs became available, the American Telephone & Telegraph Co. agreed to provide this equipment through the Alexander Graham Bell Association for the Deaf. Teletypewriters for the Deaf, Inc. (TDI) was independently formed by members of the Bell Association and of the National Association of the Deaf to handle the acquisition, reconditioning, and installation. This effort was greatly assisted by participation of members of the Telephone Pioneers of America. Simultaneously, several deaf members of the Bell Association, operating as Applied Communications Corp., initially manufactured the modems which accompanied the TTYs. TDI provided information on TTY use, published a directory, and made loans available to consumers.

Between 1972 and 1973, video screen and other electronics technology was introduced into the system, leading TTYs and the newer self-contained equipment to be called telecommunications devices for the deaf (TDDs).

Sections 503 and 504 of the Rehabilitation Act of 1973 as amended in 1978, implementing the civil rights of handicapped people, pushed the installation of TDDs in emergency services, government offices, and private businesses. An estimated 50,000 to 100,000 stations were in use in 1981.

The case study next discusses the problems faced by the system and some accomplished solutions. Because of the slowness of typing compared to voice, a TDD call takes four times as long to convey the same information. Long distance costs, at the same rate as voice, are then quadrupled for TDD conversations. Through the lobbying of the National Center for the Law and the Deaf, 42 States between 1977 and 1981 lowered their interstate rates by as much as 75 percent. In 1981 AT&T lowered its TDD daytime long-distance interstate rates by 35 percent and its evening rates by 60 percent, but had not decided on its certification process.

TDDs and modems have generally been expensive, ranging from $550 and up, installed. Recently, however, some portable models have been avail-

able for $225. Some States rent units by the month for $15 to $36, and some give the option to buy. In 1979, the California legislature called for free distribution of TDDs to the certified hearing-impaired. A 15¢ per month surcharge on all California telephone users supports a trust fund to carry out the law. By July 1982, however, ony 4,000 free TDDs had been installed in that State.

The modern computer network uses an 8-level American Standard Code for Information Interchange (ASCII) which is much faster but is incompatible with the TDD Baudot code, therefore excluding the TDD system from over 4 million ASCII stations. Private manufacturers now produce a dual TDD and converter that can turn a Baudot machine into an ASCII compatible one. California installs a TDD capable of handling both codes. As the computer market expands, the case study suggests the prices of TDDs should fall. Demands remain for the installation of TDDs in more public places such as shopping malls, public transportation stations, and other such areas.

Prepared by: Virginia W. Stern and Martha Ross Redden. Published in December 1982 as *Background Paper #2: Selected Telecommunications Devices for Hearing-Impaired Persons* (20 pp., 47 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *Technology and Handicapped People* (Washington, D.C.: U.S. Government Printing Office, May 1982).

Available from: U.S. Government Printing Office, stock #052-003-00898-0, $3.50. National Technical Information Service, order #PB 83-169 292.

CASE STUDY #22

The Effectiveness and Costs of Alcoholism Treatment

This case study on the effectiveness and costs of alcoholism treatment was prepared as part of OTA's project on "Medical Technology and Costs of the Medicare Program," and answers the specific request by the Subcommittee on Health of the Senate Committee on Finance for scientifically based information on the effectiveness of alcoholism treatments.

The goal of this case study is to provide scientific background for congressional consideration of Medicare reimbursement for alcoholism treatment services. In addition to describing the problem posed by the abuse of alcohol, the study seeks to assess, on the basis of scientific research evidence, treatment programs and services developed to aid alcoholics. Because of the limitations of the available literature—i.e., for some treatments, no scientific studies are available, and for some others, the available evidence on outcomes is not sufficient to permit unambiguous conclusions—the study's conclusions are necessarily limited.

Alcoholism constitutes a vast syndrome of medical, economic, psychological, and social problems. From 10 million to 15 million Americans are either alcoholic or have serious problems directly related to the abuse of

alcohol. Up to 35 million more individuals are estimated to be affected indirectly.

The economic cost of alcoholism and alcohol abuse, a major portion of which is lost work productivity, may be as high as $120 billion annually. Furthermore, alcohol abuse may be responsible for up to 15 percent of the Nation's health care costs. Alcoholics use significantly greater amounts of medical services than do nonalcoholics for a wide range of physical problems caused by or associated with excessive drinking.

Despite the significance of problems relating to alcoholism and alcohol abuse and the increasing attention of health professionals to these problems, an estimated 85 percent of those with problems due to alcohol use receive no treatment for their condition. For the small proportion of alcoholics or alcohol abusers actually receiving treatment, the aggregate costs of treatment have risen substantially. In 1982, Medicare alone spent an estimated $150 million for the treatment of alcoholism. Modalities of treatment for alcoholism include the use of drugs, psychologically based treatments, and treatments based on group and community efforts. As the debate over rising health care costs has intensified, questions have been raised about whether the treatments provided are effective.

Most of the existing literature on the effectiveness of alcoholism treatment is not of very good methodological quality. The available research evidence seems to indicate that any treatment of alcoholism is better than no treatment. There is little evidence that any one treatment or treatment setting is better than any other. Further research is needed both to specify how to match patient to treatment and setting and to test competing claims of effectiveness.

A number of private insurance companies, employers, and the Federal Government have recently expanded benefits for alcoholism treatment because it appears that the costs of not providing alcoholism treatment are greater than the costs of providing such treatment. The essential question at this point seems to be not whether reimbursement for the treatment of alcoholism should be provided, but whether current reimbursement policy supports the provision of the most cost-effective treatments.

Although reimbursement formulas are complex, it is generally accurate to state that reimbursment systems, particularly Medicare and Medicaid, have encouraged the use of inpatient, medically based treatment for alcoholism. The available evidence seems to indicate that medically based inpatient rehabilitation services are far more expensive, but not necessarily more effective, than primarily nonmedical inpatient or outpatient treatment.

Prepared by: Leonard Saxe, Denise Dougherty, Katharine Esty, and Michelle Fine. Published in March 1983 as Case Study #22 (98 pp., 353 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *Medical Technology and the Costs of the Medicare Program* (Washington, D.C.: U.S. Government Printing Office, July 1984).

Available from: U.S. Government Printing Office, stock #052-003-00902-1, $5.50. National Technical Information Service, order #PB 83-192 492.

CASE STUDY #23

The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis

This case study discusses and examines the issues and evidence surrounding the safety, efficacy, and cost effectiveness of therapeutic apheresis. It was prepared as part of OTA's project on "Medical Technology and Costs of the Medicare Program," and responds to a specific request by the Senate Finance Committee Subcommittee on Health for scientifically based information on the effectiveness of the therapeutic apheresis.

In the past decade, the medical community has increasingly used therapeutic apheresis, a technology whereby a patient's plasma and/or blood cellular parts are separated and then removed from the blood and replaced by substitute plasma or a related physiological solution. It is believed that abnormal or harmful substances of cells are thereby removed, leading to an arrest or even cure of the disease.

Approximately 5 percent of therapeutic apheresis procedures are performed manually by removing whole blood, spinning it down in a stationary centrifuge, and returning the cellular components to the patient. For most apheresis procedures, however, automated centrifuge equipment is used. Some new major developments in hardware, including adsorption columns and semipermeable membranes that function as molecular sieves, are now either undergoing clinical tests or about to be marketed for general use. These advances in equipment may, in the course of the next decade, be improved or even overshadowed by advances in basic biomedical research or by emerging developments such as biotechnology.

By almost any standard however, present treatment by apheresis is still in relatively early stages of development—there are no ideal protocols based on a complete understanding of reasons for its efficacy. As a result, much of the existing literature on the effectiveness of apheresis is not of very good methodological quality. The great majority of the reported studies are case reports without any conclusive control groups, blinding, randomization, or other techniques used in controlled clinical trials. Furthermore, the assessment of individual treatments is difficult, because apheresis procedures are often provided in combination with drug therapy or other treatment regimes. Because of these and other limitations, indications from the available research evidence about the safety, efficacy (under ideal conditions of use), and effectiveness (under average conditions) of apheresis are necessarily limited, although some tentative conclusions and directions for treatment can be discerned.

Apheresis appears to be a relatively safe procedure, though it is not without at least short-term risks. The long-term risks of removing useful blood components have been termed "worrisome" and are unclear at best. Apheresis device equipment can also be termed effective in the sense that the technology accomplishes the intended removal of plasma and cells. However, there is very little definitive evidence documenting the widespread success of the technology in actually improving health. The use of apheresis

has been generally acknowledged as an effective treatment for acute therapy in a small group of relatively obscure diseases, including acquired myasthenia gravis, primary macroglobulinemia (Waldenstom's) and hyperglobulinemia, including multiple myeloma. There is certainly suggestive evidence, too, that therapeutic apheresis is successful in arresting the disease process for some patients with other specific disease conditions. Convincing proof of clinical efficacy, however, is still lacking in the wider variety of diseases in which this treatment is being used.

National expenditure estimates on apheresis therapy, which is currently performed routinely on only selected patients, range from $3.2 million to $240 million. In the event that apheresis therapy is extended in the future to the wider array of diseases for which it has been only experimentally applied thus far, however, total treatment costs could increase to from $650 million to over $7 billion per year.

Third-party payment will be an important influence on future adoption, use, and economic effects of therapeutic apheresis, through the funding and reimbursement policies of both private and government insurance programs. Reimbursment policies, like other aspects of therapeutic apheresis, have been the subject of some debate because of the competing factors of cost and therapeutic promise. The development of most of these policies has been recent. The Health Care Financing Administration announced coverage in September 1981 under the Medicare program for only a small group of relatively rare disease indications. Other governmental programs, as well as private medical insurers, vary on which disease indications should be covered, probably because the scrutiny of the evidence on safety and efficacy has not been consistent. A widening of Medicare and private insurer coverage of therapeutic apheresis for specific life-threatening complications (e.g., rheumatoid vasculitis) is probable in the near future. But direct cost estimates and the potential cost of possibly premature diffusion alone make it unlikely and unwise that third-party payers support any broad extension of benefits for apheresis treatment until more valid data are generated. Research efforts and clinical trials are currently, being conducted for several disease applications of importance, and these could define more precisely what advantages, if any, apheresis treatments may have. But until evidence is available, therapeutic apheresis will largely be viewed as an experimental technique, not to be considered as a part of routine care.

Prepared by: Office of Technology Assessment. Published in July 1983 as Case Study #23 (165 pp., 154 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Medical Technology and the Costs of the Medicare Program* (Washington, D.C.: U.S. Government Printing Office, July 1984).

Available from: National Technical Information Service, order #PB 84-114 842.

CASE STUDY #24

Variations in Hospital Length of Stay: Their Relationships to Health Outcomes

Length of stay (LOS) in acute care hospitals varies greatly across the United States. Eastern hospitals exhibit lengths of stay that are about 40 percent higher than western hospitals. These differences have remained remarkably consistent over the past 15 years. They are unexplained by differences among regions in age, sex, or race distributions. Current research has also been unable to demonstrate that differences in severity of illness across regions explain any of the variations. This possibility must remain at least somewhat open, however, since there has been little research at the most detailed clinical level trying to find subtle but clinically important differences in case mix among regions within specific disease categories. Available evidence suggests that physicians in different regions treat patients with the same illnesses differently with respect to LOS.

The potential economic significance of these LOS differences is very large. If all patients 65 years of age and older had experienced the West's LOS in 1980, those hospitalized in regions outside the West would have spent 21 million fewer days in the hospital, thus reducing total days in the hospital for this age group by 20 percent. How much of the potential savings could actually be realized depends entirely on how LOS is reduced, whether admission rates rise in compensation, and whether hospitals remove acute care beds from service in response to decreased occupancy. There is almost no research in this area.

Before designing new programs to reduce LOS, however, one must ask whether these regional differences in LOS are associated with differences in health outcomes. Are patients in the East harmed because they stay in the hospital longer than their western counterparts? Or are patients in the West suffering because they leave the hospital too early? Either, both, or neither of these possibilities may be true.

A great deal of research has studied the association of LOS with factors such as hospital ownership, area hospital bed supply, teaching status, occupancy rate, and other hospital charactertistics with varying results. Very little research has been done on the relationship between regional LOS differences and health outcomes. Very little attention has been devoted to ascertaining precisely how physicians manage the same kinds of illnesses in different regions of the country, trying to explain regional LOS differences by finding differences in physician practices.

This review attempted to find data in the medical research literature clearly establishing a particular LOS for specific illnesses. Regions above the standard would be judged as having lengths of stay that were too long. Those below the standard would be judged too short.

Studies with scientifically sound methods were found in five clinical areas: acute myocardial infarction, elective surgery, low-risk newborn deliveries, low birthweight infants, and psychiatric hospitalization. Studies in the first four areas uniformly concluded that shorter lengths of stay had no different

outcomes from the more traditional, longer lengths of stay. None of the studies was large enough to exclude a small, but important negative health impact of early discharge. Many of the studies excluded the elderly. In the area of psychiatric hospitalization, the evidence is stronger that patients hospitalized initially for shorter periods do better than patients kept longer. Even in this area, however, the studies each assessed different patient groups and employed widely varying definitions of early (11 to 86 days) and late (24 to 179 days) discharge. Thus, the medical literature failed clearly to establish LOS standards for any clinical condition.

Because the economic benefit of decreasing LOS to western levels is unclear and because the possibility of such a program having a negative health impact has not been excluded, the case for reductions in eastern lengths of stay is very weak. Further research will be necessary to establish the relationship between length of hospital stay and health outcomes.

Prepared by: Mark R. Chassin. Published in August 1983 as Case Study #24 (85 pp., 185 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Medical Technology and the Costs of the Medicare Program* (Washington, D.C.: U.S. Government Printing Office, July 1984).

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CASE STUDY #25

Technology and Learning Disabilities

Current definitions of learning disabilities refer to a set of disorders that affect reading, handwriting, spelling, mathematics, listening, expressive language, and social skills. By definition, learning disabilities are not caused by a lack of intelligence; sensory impairment (like deafness); primary emotional disturbance; or environmental, cultural, or economic disadvantage. This definition thus excludes all commonly accepted impediments to learning except neurological impairment. The theories, treatments, and investigations of the learning disabilities field frequently reflect the exclusionary approach of the definition. Learning disabilities are recognized primarily as school-related problems.

In the last decade, however, a growing number of experts in the field have come to see learning disabilities as arising from an interaction of neurophysiological with psychological, educational, and social factors. The neurophysiological factors are seen as necessary but perhaps not sufficient to explain the nature and prevalence of learning disabilities. Although the precise nature of these neurophysiological factors is yet elusive, the concept of learning disabilities seems to require a neurophysiological component as a sine qua non, setting learning disabilities as a group of disorders that merit legislative attention and support.

In this case study, a systems approach is applied to learning disabilities. This approach is a comprehensive rather than an exclusionary approach. Thus, a learning disability is seen not simply as a problem in academic learning but as a particular style of thought, performance, and expression that

can affect one's entire life. A learning disability is seen not as specific to school settings but as involving the family, the community, the immediate environment, and progressively farther-reaching environments. Rather than being seen as having a single cause, a learning disability is seen as the outcome of a network of forces that include the neurophysiological, emotional, familial, organizational, political, social, historical, and technological. The case discusses possibilities for research and development based on this integrative view.

In this case study, both "hard" and "soft" technologies relevant to the learning disabled are discussed. "Hard" technology refers to concrete discoveries and inventions such as facts about the brain and microcomputers. "Hard" technology is the **what**. "Soft" technology refers to **how** the technology is used and **who** uses it. The complex of legislation, private and public organizations, programs, theories, and research are all "soft" technologies. These "soft" inventions provide the social context for "hard" technologies. The case study argues that unless this social context is addressed, the promise that advanced "hard" technology holds for learning-handicapped people might be seriously compromised.

Prepared by: Candis Cousins and Leonard Duhl. Published in December 1983 as Case Study #25 (63 pp., 216 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Technology and Handicapped People* (Washington, D.C.: U.S. Government Printing Office, May 1982).

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CASE STUDY #26

Assistive Devices for Severe Speech Impairments

Lack of speech is a serious disability. When combined with other disabilities that render a person functionally unable to write or type, it is more serious still. Whatever their age and whether or not they are of normal intelligence, people with such disabilities are very likely to be placed in institutional care. And if they are people who—because of a genetic defect, an accident during gestation or an injury at birth—have never talked, chances are they will be assumed to be profoundly mentally retarded and so will also have been deprived of that education without which no one in this society can aspire to enter the work force or to live as an independent adult.

As recently as the mid-1970s, there was little or no remedy for either the congenital or the acquired inability to speak when accompanied by severe physical disability. Affected individuals could often communicate with those in their immediate circles by resorting to eye signals, other forms of private language, or the use of primitive language boards. But the emotional and intellectual content of such interactions was limited, consigning these people to social isolation, passivity, and custodial care.

This case study is about the revolution in communication aids that has since changed the outlook for this population, its accomplishments to date, its promise for the future, and its problems. It also discusses related public policy and the barriers to fully utilizing the technology now available for the benefit of the individuals in question, their friends and families, and society as a whole.

Prepared by: Judith Randal. Published in December 1983 as Case Study #26 (50 pp., 52 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Technology and Handicapped People* (Washington, D.C.: U.S. Government Printing Office, May 1982).

Available from: National Technical Information Service, order #PB 84-175 371.

CASE STUDY #27

Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial, and Policy Analysis

The case study entitled "Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial, and Policy Analysis" provides a "snapshot" view of the scientific and clinical status of nuclear magnetic resonance (NMR) imaging, as well as an overview and analysis of the impact of various Federal and non-Federal policies and practices on the development and diffusion of NMR imagers as of August 1984. The policies examined include the Food and Drug Administration (FDA) premarket approval (PMA) process; Health Care Financing Administration (HCFA), Blue Cross/Blue Shield (BC/BS), and commercial insurance company reimbursement decisions; State certificate-of-need (CON) policies; and Federal financial support for research and development.

NMR imaging is an exciting new diagnostic imaging modality that has captured the interest of the medical and scientific communities and the general public. NMR imagers employ radiowaves and magnetic fields rather than ionizing radiation, thus eliminating the risk of X-irradiation associated with use of devices such as X-ray computed tomography (CT) scanners. NMR imagers not only produce images with excellent spatial and contrast resolution without the need for injection of potentially toxic contrast agents, but also enable physicians to visualize areas such as the posterior fossa, brain stem, and spinal cord that until now have not been well seen with other noninvasive imaging techniques. In addition, because NMR imagers are sensitive to fundamental physical and chemical characteristics of cells, the technique offers the *possibility* of detecting diseases at earlier stages than is currently possible and of permitting accurate diagnoses to be made noninvasively.

NMR imagers are diffusing very rapidly. In January 1983, 14 units were installed in the United States. By October 1983, 34 units were in place in the United States, and by August 1984, at least 145 units had been installed worldwide, of which 93 were in the United States.

NMR imagers are the first imaging devices for which FDA premarket approval has been required under the 1976 Medical Device Amendments. In the case of NMR, the PMA process appears to be playing primarily a quality assurance role. PMA does not appear to have constrained NMR technological development or the number of NMR imagers that could be installed in the United States on an experimental basis. The PMA process may prove capable of conferring an important competitive advantage upon those manufacturers who are first to receive PMA, a possibility which could affect the speed with which manufacturers pursue development of new technologies in the future.

Third-party payers are now in a position of major influence over the rate at which NMR imagers are acquired. Although some local BC/BS plans and some commercial insurers have begun to pay for NMR scans, neither HCFA nor national BC/BS have completed the assessments that will determine their payment policies and recommendations. Delays in reimbursement coverage will slow diffusion of NMR imagers. Future HCFA decisions regarding recalibration of diagnosis related groups (DRG) payment rates as part of Medicare's prospective hospital payment system will also affect hospital decisions regarding acquisition of NMR scanners in the future.

State CON policies appear to be having several effects on the diffusion of NMR imagers. They are delaying the acquisition of NMR devices by some hospitals, speeding acquisition by others, and promoting the placement of NMR imagers in outpatient diagnostic centers, which are not subject to the same CON controls as hospitals. The status of State CON policies and decisions is reviewed in the case study.

Prepared by: Earl P. Steinberg and Alan B. Cohen. Published in September 1984 as Case Study #27 (156 pp., 207 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Federal Policies and the Medical Devices Industry* (Washington, D.C.: U.S. Government Printing Office, October 1984).

Available from: U.S. Government Printing Office, stock #052-003-00964-1, $5.50. National Technical Information Service, order #PB 85-146 207.

CASE STUDY #28

Intensive Care Units: Costs, Outcome, and Decisionmaking

This case study was prepared as part of OTA's project on "Medical Technology and Costs of the Medicare Program." This case study provides an overview of the development of intensive care units (ICU) and their rapid diffusion into medical practice. It presents information on their utilization costs and reimbursement. It also describes various measures of outcomes of intensive care and reviews the outcome literature. Finally, the intricacies of decisionmaking in the ICU are discussed, and policy implications are presented.

Almost 80 percent of short-term general hospitals have at least one intensive care unit. Overall, in 1982, 5.9 percent of total hospital beds in non-Federal, short-term community hospitals were beds in intensive and coronary care units. Over the 6 years to 1982, the number of ICU beds rose about 5 percent a year, compared to a rise in general hospital beds of only 1 percent a year.

For a number of reasons, an accurate estimate of the national cost of ICU care is difficult to make. The national average per diem charge in 1982 was $408 compared to a regular bed per diem charge of $167, a ratio of about 2.5:1. However, it is likely that the true cost ratio is closer to 3.5:1. In addition, ICU patients consume a greater proportion of ancillary services than patients on regular floors. Based on these and other considerations, it is estimated that the costs of adult intensive care—the cost to the hospital of patients while they are in the intensive care unit—represents about 14 to 17 percent of total inpatient, community hospital costs, or $13 billion to $15 billion in 1982. Inclusion of the other types of specialized, intensive care units, such as burn units and neonatal intensive care units, would bring the percentage of total inpatient hospital costs attributable to intensive care to about 20 percent.

Unfortunately, it is difficult to separate the intensity of care from the setting in which it is provided, and therefore, to know whether intensive care would be as effective if provided on the general medical floor as on the physically and administratively separate ICU. A recent consensus panel sponsored by the National Institutes of Health found that it is impossible to generalize about whether ICU care improves outcome for the varied ICU patient population. Nevertheless, for most severely ill and injured patients, care in an ICU has become the accepted and standard mode of treatment in the United States.

The representation of the elderly in ICUs seems to be the same or slightly more than in the hospital as a whole. Poor chronic health status, rather than age, appears to be a predominant factor that limits the use of ICUs in individual cases in the United States.

Recent data have emphasized the inverse relationship between the cost of care and survival. At this time, there are no accepted methods for determining ahead of time which patients will benefit from additional ICU care. From a number of studies it is clear that the sickest ICU patients, many of whom do not survive consume a highly disproportionate share of ICU costs.

Under the new Medicare prospective pricing payment system, based on diagnosis-related groups (DRGs), the sicker ICU patients will become financial "losers" to the hospital. Yet, the new incentives of the DRG payment system are being imposed on a decisionmaking environment in which the cost of ICU care has been of relatively minor concern. Indeed, the traditional decisionmaking process related to ICU patients has often led physicians to provide ongoing intensive care after the initial rationale for doing so no longer exists. The relatively recent concern about health care costs

as well as the increasing desire by patients and families to forego life-sustaining treatment in some situations may alter prevailing provider attitudes regarding provision of intensive care. ICU decisionmaking will become even more difficult than it has in the past due to potential financial, moral, and ethical conflicts between patients, physicians and hospitals.

Prepared by: Robert Berenson. Published in November 1984 as Case Study #28 (98 pp., 283 refs.). Associated main report was Office of Technology Asessment, U.S. Congress, *Medical Technology and Costs of the Medicare Program* (Washington, D.C.: U.S. Government Printing Office, July 1984).

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CASE STUDY #29

The Boston Elbow

The Boston Elbow is an artificial arm, battery-powered and myoelectrically controlled—i.e., controlled by signals from an amputee's stump muscles. It reproduces one active movement of the human arm, elbow flexion and extension. The Boston Elbow is technologically distinctive, but it is only one way to compensate for the loss of an arm. Nonprosthetic measures as well as competing prostheses are available to most amputees.

Distribution of the Boston Elbow and other compensatory options is at least in part a function of public policy, especially the design and implementation of disability benefits programs. For policy purposes, people (excluding children) with disabilities seem to fall into three groups—veterans, workers, and citizens—each with eligibility criteria set by law. The amputee-veteran has many alternatives to the Boston Elbow, including an elbow prosthesis that originated at the Veterans Administration. The amputee-worker faces three sets of circumstances:

- If injured in the workplace, he or she is eligible for workers' compensation benefits, including monetary compensation and prosthetic devices.
- Amputees are most likely to be fitted with a Boston Elbow if their employer's insurer is the Liberty Mutual Insurance Co.; Liberty Mutual financed design of the device and continues to develop and manufacture it.
- Workers with long-term disabilities who have paid into the Social Security system receive Disability Insurance benefits in the form of cash payments and Medicare program coverage.

The latter may provide a Boston Elbow, but program coverage becomes a benefit only 24 months after the onset of disability.

Disabled individuals judged to be potential workers are entitled to enter the Federal/State Vocational Rehabilitation Program and receive the services required for their rehabilitation. Potential workers are thus entitled to a Boston Elbow, but they must compete for limited Vocational Rehabilita-

tion moneys. The amputee-citizen is unlikely to be provided with a Boston Elbow, but Federal policies do create relevant research by the National Institute of Handicapped Research, regulation by the Food and Drug Administration, and legislated restatements of disability issues, such as the Rehabilitation Act of 1973. The Boston Elbow fares differently in different programs, and although this can be difficult for the amputee, it is the result of explicit mandates, institutional histories, and ongoing allocation of public resources.

Prepared by: Sandra J. Tanenbaum. Published in November 1984 as Case Study #29 (44 pp., 47 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Federal Policies and the Medical Devices Industry* (Washington D.C.: U.S. Government Printing Office, October 1984)

Available from: U.S. Government Printing Office, stock #052-003-00972-2, $2.25. National Technical Information Service, order #PB 85-145 936.

CASE STUDY #30

The Market for Wheelchairs: Innovations and Federal Policy

Wheelchairs, for many disabled persons, are essential medical devices for work, mobility, and recreation. The characteristics, prices, and durability of these chairs are critical both to the quality of life of their users and to the costs incurred by the users, insurers, and government agencies. This case study focuses on how Federal policies affect innovations in wheelchair characteristics.

The case study examines the wheelchair market and notes that one American in 200 (approximately 1.2 million total in 1977) is a wheelchair user. In 1982, an estimated 338,000 wheelchairs of all types were sold in the United States, for total retail sales of $126 million. The market is dominated by a few large firms, which suggests that the wheelchair market is oligopolistic.

Purchase costs of a wheelchair vary from $200 to $3,000, depending on the type of wheelchair (manual, power, sports, or power alternative), the number of accessories and custom features, the quality of the construction and materials, and the manufacturer. Maintenance and repair costs of wheelchairs are substantial. Over an average 3- to 4-year wheelchair lifetime, cumulative repair costs are sometimes more than initial purchase costs. The study compares the costs of different wheelchair models using total annualized costs.

The wheelchair market is dominated by third-party reimbursement. About half of all wheelchair purchases are at least partially funded by government and another 40 to 45 percent by private insurers. Only 5 to 10 percent are paid for totally by the user. The extensive amount of third-party reimbursement steers innovation to devices that can expect to receive such funds. Although all insurers will pay for a wheelchair that is "medically necessary," the meaning of this term and insurers' policies vary. The

emphasis on price over performance in the reimbursement procedures for general manual wheelchairs has probably discouraged innovation.

The case study also discusses Federal policies relating to wheelchairs. Government research and development efforts on wheelchairs appear modest in relation to the number of users. However, the Federal Government is a major purchaser of wheelchairs through the Veterans Administration, Medicaid, and Medicare.

Wheelchairs themselves are covered under legislation concerning medical devices. The Food and Drug Administration classifies and regulates the marketing of medical devices, including wheelchairs.

Eleven wheelchair manufacturers were surveyed by telephone interview regarding their innovations in the last decade, their research and development efforts, their marketing methods, and the effect of government policies upon their operations. The results indicated that most innovations have been refinements of existing products, with an emphasis on usefulness to active users.

The case study also presents two examples of innovations in wheelchair design, the Power Rolls© IV, made by Invacare Corp., and a curb-climbing wheelchair available in parts of Europe, but not the United States. Finally, public policy issues related to the wheelchair industry are discussed.

Prepared by: Donald S. Shepard and Sarita L. Karon. Published in November 1984 as Case Study #30 (68 pp., 42 refs.). Associated main report was: Office of Technology Assessment, U.S. Congress, *Federal Policies and the Medical Devices Industry* (Washington, DC: U.S. Government Printing Office, October 1984).

Available from: U.S. Government Printing Office, stock #052-003-00973-1, $3.00. National Technical Information Service, order #PB 85-145 944.

CASE STUDY #31

The Contact Lens Industry

This case study presents an analysis of the contact lens industry in the United States. The study includes descriptions of the historical evolution of contact lenses; the range of available lens types; the characteristics of wearers of contact lenses, how much they spend, and the sources of payment for these contact lenses expenditures; the firms that make them; the eye-care professionals who represent the bridge between makers and users by prescribing and fitting contact lenses, and toward whom lens manufacturers direct most of their marketing efforts; and the effects of Federal policies on the industry. The case study also analyzes the relationship between industry structure and behavior, or the influence that the number, size, market power, and policies of the makers of contact lenses have on their incentives and behavior regarding competition in product development and price.

The role played by public policy in influencing this competition, either directly or indirectly, is also analyzed. The more important elements of public policy affect: 1) mergers, 2) market entry, 3) competition in the professional prescribing and fitting of contact lenses, and 4) the payment mechanism in the purchasing process.

Contact lenses are of three types: hard lenses, soft lenses, and gas-permeable lenses. About 120 million people in the United States wear corrective eyeglasses, and another 16 million to 18 million use contact lenses.

Among all U.S. contact lens wearers, the use of hard lenses is declining and the use of soft and gas-permeable lenses is increasing. In the future, soft and gas-permeable lenses will account for almost all contact lens sales, and they may become as common or even more common a method of vision correction than eyeglasses if their comfort, wearability, applications, and effectiveness continue to increase.

Although a large number of firms produce contact lenses, manufacturers of both soft and gas-permeable lenses are concentrated among a few large firms. However, because of many factors—e.g., the similarity of lenses within each type, the considerable substitutability and resulting competition among types, and excess capacity—competition is active in both product development and price. Where market power is most evenly distributed (hard lenses), price competition is greatest. Where large firms dominate but are surrounded by a fringe of smaller firms (soft lenses), price competition is high. Where only a few firms are in the market and one predominates (gas-permeable lenses), price competition, among groups if not within this group, is at least observable.

To the present, the history of this industry shows the important role of small firms, but the sector most open to small firms—hard lenses—is becoming less important. In the area where small firms have difficulty in entering the market—soft lenses, mergers and acquisitions by large firms may eliminate many of the energetic small firms. And small firms have the greatest difficulty in entering the fastest growing market area—gas-permeable

lenses. The U.S. Food and Drug Administration's premarketing approval policies have been especially burdensome to smaller firms. Strict market approval policies may be wise for significantly new lens types, but once their effectiveness and safety become established, more flexible approaches toward minor or closely similar new developments seem warranted.

The degree of competition among dispensers of contact lenses has an especially strong impact on the prices consumers ultimately pay for their lenses, since the professional services required to examine the eye and to choose and fit the lenses are a major component of the total cost of obtaining contact lenses. State laws directly or indirectly prohibiting price advertising by professionals have been severely narrowed by the Federal Trade Commission, causing increased price competition among lens care providers and the entry of large optical chains that price their services low and pull down prices charged by other providers.

For the most part, patents neither pose problems nor exert special influence on the contact lens industry, although patents can reserve superior materials, designs, and processes for one or a few firms to the disadvantage of others.

Prepared by: Leonard G. Schifrin and William J. Rich. Published in December 1984 as Case Study #31 (70 pp., 57 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Federal Policies and the Medical Devices Industry* (Washington DC: U.S. Government Printing Office, December 1984).

Available from: U.S. Government Printing Office, stock #052-003-00981-1, $3.00. National Technical Information Service, order #PB 85-204 451.

CASE STUDY #32

The Hemodialysis Equipment and Disposables Industry

End-stage renal disease (ESRD) afflicts approximately 96,000 people in the United States. In the course of treatment for this disease, most patients and their providers use an array of products produced by the hemodialysis equipment and supplies industry. This case study offers an economic analysis of this relatively new U.S. industry. Its existence is a consequence of modern medical advances that have made hemodialysis a viable treatment for ESRD. Moreover, it would be difficult to think of another industry that has been so clearly and directly shaped by Federal policy.

Federal policy continues to be critical to the industry's development. Recent Federal initiatives have changed the rules under which treatment for ESRD is reimbursed. Federal policymakers are also being asked to evaluate certain current practices in treatment. The decisions made will influence, to a significant degree, the structure and economic performance of the industry.

The market for dialysis equipment and disposables has undergone rapid growth since 1972 when Congress passed legislation extending Medicare coverage to patients with ESRD, regardless of age. Since its inception the

number of beneficiaries of this program has grown by more than 700 percent. The firms that produce dialysis equipment and disposables now have total sales of roughly $500 million. Although profits in the industry were apparently quite attractive several years ago, they have been increasingly squeezed. The price of dialyzers, which constitute about 40 percent of the industry's sales, has fallen by 34 percent in real dollars over the past 5 years.

Future prospects for the industry will largely depend on the resolution of some major policy issues. Three areas of policy in particular are considered in this case study: the reimbursement procedures for dialysis care, the Federal contribution to research on ESRD, and the practice of "reuse" of dialyzers.

Perhaps the most notable and most controversial of these issues is the new Federal reimbursement rules for the ESRD program that were established in 1983. These rules are aimed at controlling program costs, in particular by encouraging home dialysis. The rules are likely to have a myriad of direct and indirect effects on the nature of care and thus on the hemodialysis equipment and disposables industry. The industry will certainly survive the new rules, although its form and structure may undergo some change. Profitability will depend on how facilities and patients respond to the rules and on how creatively the industry can react.

The second major policy issue concerns research. The Federal Government has supported considerable research on ESRD and has contributed to the development of many of the products sold by the equipment and disposables industry. However, this Government research contribution has declined, particularly in the area of maintenance dialysis, the area most likely to affect the industry. The long-term consequences are likely to be a decline in innovation in the industry.

The third major issue facing the industry involves dialyzer reuse. Increasingly, dialyzers, which are labeled by manufacturers for single use only, are being reprocessed and used again, often multiple times. From an economic perspective, reuse appears attractive due to the cost savings involved. However, critics of the practice express concern about the possible adverse consequences for patients. If reuse is associated with increased morbidity or mortality, such costs would have to be included in any cost analysis. Although projected direct cost savings are large, they could be outweighed by the indirect costs of adverse medical consequences. The Federal Government has an interest in the growth of appropriate reuse of dialyzers but needs to be concerned with ensuring that adequate reprocessing and quality control procedures be undertaken.

Prepared by: Anthony A. Romeo. Published in December 1984 as Case Study #32 (67 pp., 120 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Federal Policies and the Medical Devices Industry* (Washington, DC: U.S. Government Printing Office, December 1984).

Available from: U.S. Government Printing Office, stock #052-003-00982-0, $3.00. National Technical Information Service, order #PB 85-154 953.

CASE STUDY #33

Technologies for Managing Urinary Incontinence

Urinary incontinence is a problem that affects 5 to 10 million Americans. It can be an embarrassing, disabling, and costly health problem. Although urinary incontinence may occur at all ages, it is most common among people over age 65, and is often a major factor in admission to nursing homes. Yet despite its prevalence, relatively few studies have addressed the problem of urinary incontinence.

This case study attempts to draw together conclusions from previous studies, discussing the problem, costs, and treatment of urinary incontinence. It describes medical devices and other technologies used to manage urinary incontinence and reports on the industry that produces such devices.

The case study points out that there are several types of urinary incontinence, each with a unique cause and treatment. Causes include physiological factors such as urinary tract infection, weakened pelvic musculature, and neurological disorders. In addition, incontinence may be caused by external factors including impairment of access or mobility.

In view of the variety of causes, a diagnostic evaluation is recommended for proper treatment. Published reports of the effectiveness of treatments are reviewed in this case study, which focuses especially on medical devices such as artificial sphincters, electrical stimulation, catheters, and bedpads.

The study also assesses the costs of urinary incontinence. "First-order" costs (i.e., the costs of managing incontinence without including the costs of any complicating conditions) are estimated to be between $0.5 and $1.5 billion per year in nursing homes in the United States. This figure does not include "second-order" costs, which arise out of treatment complications such as urinary tract infections associated with in-dwelling catheters.

Prepared by: Joseph Ouslander and Robert Kane. Published in July 1985 as Case Study #33 (75 pp., 180 refs.). Associated main report Office of Technology Assessment, U.S. Congress, *Federal Policies and the Medical Devices Industry* (Washington, D.C.: U.S. Government Printing Office, October 1984).

Available from: U.S. Government Printing Office, stock #052-003-00999-4; $3.25. National Technical Information Service, order #PB 85-240 208.

CASE STUDY #34

The Cost-Effectiveness of Digital Subtraction Angiography in the Diagnosis of Cerebrovascular Disease

Digital subtraction angiography (DSA) is one of several computer-assisted radiologic tools for diagnosing conditions associated with the internal structure of blood vessels (particularly arteries). This case study examines the cost-effectiveness of DSA in the diagnosis of cerebrovascular disease. It provides an analysis of the relative cost of DSA compared to conventional ar-

teriography, using information available in the early 1980s (the analysis was completed in 1983). The study describes potential applications of DSA and discusses implications for future clinical practice and patient care costs.

An overview of the clinical problems of cerebrovascular disease and stroke is presented. The study discusses the extent and implications of the illness in the population and then introduces the theory of preventive therapy. The importance of new medical techniques to help in the early diagnosis of stroke is emphasized.

The study takes an indepth look at DSA technology, particularly intravenous DSA. The technique involves injecting contrast medium into the veins. A computer "subtracts" the images before the injection from the images after the injection to give a numerical representation of the arterial structure. At the time of the study, DSA remained less accurate than conventional arteriography.

The introduction of DSA, however, makes available a less costly, relatively low risk, and highly accurate source of similar diagnostic information available through arteriography. The study highlights efficacy and safety as two important advantages of DSA.

The costs of DSA are described. Direct costs consist of capital costs (computers, X-ray equipment, and facilities) and operating costs (personnel and supplies). Other costs, such as implicit and intangible costs, costs related to diffusion, and social costs are discussed. The study considers the operational efficiency of each DSA facility, as well as the resultant efficiency of conventional arteriography facilities in analyzing these costs.

In examining the cost-effectiveness of DSA, the study compares "cost per procedure" and "cost per lesion" with the same data found for arteriography. The study suggests that DSA can be cost-effective if physicians use it as a substitute for, rather than a supplement to, conventional arteriography. [This has not happened to date.]

The study concludes that given the high quality of DSA for the study of cerebrovascular disease, the relatively low risk of morbidity, and the lack of need for hospitalization in applying the procedure, an increasing number of patients will undergo DSA evaluations in the future.

Prepared by: Matthew Menken, Gordon H. DeFriese, Thomas R. Oliver, and Irwin Litt. Published in May 1985 as Case Study #34 (56 pp., 112 refs.). Associated main report Office of Technology Assessment, U.S. Congress, *Medical Technology and Costs of the Medicare Program* (Washington, D.C.: U.S. Government Printing Office, July 1984).

Available from: U.S. Government Printing Office, stock #052-003-00998-6; $2.50. National Technical Information Service, order #PB 85-241 115.

CASE STUDY #35

The Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD)

Thirty years ago, end-stage renal disease (ESRD) was uniformly fatal. Today a variety of renal dialysis techniques and renal transplantation offer the opportunity for markedly improved prognoses for afflicted individuals. Associated with the use of these technologies, however, have been formidable costs. The most common treatment for ESRD is hemodialysis (HD) performed in the hospital or in independent dialysis centers (center HD). However, the advent of continuous ambulatory peritoneal dialysis (CAPD) in the late 1970s has dramatically changed treatment options available to the patient with ESRD.

The case study includes descriptive data on the dimensions of the ESRD problem and presents information on the physiology of and techniques for chronic renal dialysis. It then compares the medical effectiveness of HD performed in dialysis centers and hospitals with CAPD or HD performed at home. It does not compare dialysis to renal transplantation.

CAPD appears to be an acceptable alternative to HD for selected persons with ESRD. Survival rates on the two modalities appear similar, but somewhat higher overall morbidity occurs in patients on CAPD due to the frequent episodes of peritonitis that occur in some patients. No conclusion is warranted that patients' quality of life is better (or worse) on CAPD than on HD.

The case study evaluates the costs of the different types of treatment for ESRD. The differences in cost between CAPD, center HD, and home HD are sufficiently small that they can be accounted for by the variations in methods used in the available cost estimates and by case-mix differences. A conclusion that home dialysis (CAPD or home HD) is less expensive than HD in an independent center appears unwarranted.

The case study identifies critical issues that require further evaluation. The most important need is for better information by which to judge the relative effectiveness of dialysis modalities. Better information on survival, medical morbidity, and quality of life parameters all are needed. Better cost information is needed both to evaluate HCFA's 1983 reimbursement regulations and to guide policy decisions. Also, the fundamental question of who should qualify for ESRD treatment needs attention. Future research should be directed in these areas.

Prepared by: William B. Stason and Benjamin A. Barnes. Published in September 1985 as Case Study #35. Associated main report was Office of Technology Assessment, U.S. Congress, *Medical Technology and Costs of the Medicare Program* (Washington, D.C.: U.S. Government Printing Office, July 1984).

Available from: U.S. Government Printing Office, stock #052-003-01002-0; $3.25.

CASE STUDY #36

Effects of Federal Policies on Extracorporeal Shock Wave Lithotripsy

Extracorporeal shock wave lithotripsy (ESWL) is a novel technology that has been enthusiastically accepted by many patients, physicians, and hospitals as a treatment for upper urinary stones, particularly kidney stones. This case study first reviews the literature on the causes and incidence of urinary stones and on the safety and efficacy of the alternative treatment technologies. It then analyzes the effects of Federal health policies on ESWL and its integration into the American health care system.

Urinary stones are quite common, particularly among men and in certain regions of the United States. The incidence of stones has increased over time, and in 1983 approximately three out of every 2,000 persons in the United States required hospitalization for urinary stones. Many of these stones are treatable with ESWL. The actual extent of the ESWL market, however, depends on the access of physicians to the technology, the rate of use of more invasive treatment alternatives such as percutaneous lithotripsy, and the extent to which stones that could be treated with diet or drug regimens are considered eligible for ESWL treatment.

ESWL has great cost-saving potential, although its full potential may never be realized under current health payment and planning policies. The lithotripsy device is large and very expensive, and a single ESWL unit can serve a large population. If ESWL is provided in regional centers that are used to capacity, it will cost less per patient to the centers and perhaps to payers than most alternatives. But because ESWL, if available only at a small number of centers, is potentially very profitable to those centers, many hospitals, physician groups, and other organizations wish to be among those who own a lithotripter. These circumstances create strong incentives to install and use an ESWL unit, even if competition from nearby ESWL centers means the unit itself will generate little, if any, revenue greater than cost.

Three types of Federal health policies are analyzed in this study: policies governing the marketing of medical technologies, administered through the Food and Drug Administration (FDA); Federal payment policies, which affect Medicare and other Federal health programs; and Federal planning policies, which are primarily evidenced through the requirements of State Certificate-of-Need (CON) programs. The first of these policies, administered through FDA regulations, probably have their greatest effect in promoting general standards for testing and manufacture. FDA's requirements for premarket approval had relatively little effect on the speed with which Dornier was able to market ESWL technology in the United States, although these requirements may have a small effect on the speed with which competitive devices are introduced.

Federal payment policy exerts its greatest influence through the Medicare program, both because of Medicare's actual payment methods and levels and because this program is often a model for State and private payment for health care services. ESWL has been difficult to classify for the

purposes of Medicare hospital payment, and the dilemmas it has posed have illuminated the need for a systematic way to incorporate new technologies into the program. It has also illustrated some of the difficulties in Medicare physician payment, such as the difficulty in setting and maintaining an "appropriate" payment rate for an entirely new service. The extension of ESWL to ambulatory patients creates further questions regarding Medicare payment that have yet to be resolved.

The payment policies of Medicare and other Federal payers and providers, such as the Veterans Administration, both affect and are affected by ESWL. The existence of many ESWL devices will improve patient access, but it will also raise both the costs to hospitals (and other centers) of treating each patient and, under current payment arrangements, most likely the expenditures of payers. Conversely, localization of ESWL to a few regional centers may lower per-patient cost but implies more difficult access to those patients living great distances from these centers.

In theory, the planning process (as implemented through State CON laws) could both prevent overpurchase of ESWL and assure a distribution of units consistent with population size and stone incidence. In practice, the planning process will probably not achieve these goals.[1] Although in some areas the process seems to be facilitating joint purchasing and sharing arrangements, in others such arrangements have not materialized. Planning agencies in the latter areas must either choose among a number of hospitals that may be equally eligible, awarding lucrative near-monopoly rights to a few hospitals, or permit any qualified hospital to acquire one, virtually guaranteeing higher costs and lower profits.

ESWL exemplifies the service specialization and regionalization of tertiary care, as "stone treatment centers" specializing in urinary stone care proliferate. The lessons learned from current payment and planning experiences may well be applicable again as ESWL technology is turned toward treatment of gallstones, involving an entirely new set of physicians and other providers and requiring new payment levels and a new assessment of the appropriate role for ESWL.

Prepared by: Office of Technology Assessment. Published in May 1986 as Case Study #36 (108 pp., 207 refs.). Associated main report was Office of Technology Assessment, U.S. Congress, *Payment for Physician Services: Strategies for Medicare* (Washington, D.C.: U.S. Government Printing Office, February 1986).

Available from: U.S. Government Printing Office, stock #052-003-01041-1, $5.50. National Technical Information Service, order #PB 86-217 999.

[1]The statute providing Federal support for the State CON programs was repealed on Nov. 14, 1986. Health care planning through CON no longer represents Federal policy.

CASE STUDY #37

Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis

The use of nurse practitioners (NPs) and physician assistants (PAs) to provide health care traditionally provided only by physicians started during the 1960s amid widespread concern over a perceived shortage and maldistribution of physicians. Societal encouragement of this innovation in the delivery of primary health-care was based on the potential for NPs and PAs to improve access and to lower costs while maintaining the quality of care. At about the same time the number of certified nurse-midwives (CNMs), who had been providing health care for some 30 years, began to increase substantially. Today, approximately 15,400 NPs, 16,000 PAs, and 2,000 CNMs are practicing in the United States.

This case study responds to a specific request by the Senate Committee on Appropriations to examine payment for the services of NPs, PAs, and CNMs. Limitations on payment are one of many obstacles that constrain these providers from establishing a secure place in the health care system. Most third-party payers, including many Federal programs, do not cover (authorize payment for) services provided by NPs, PAs, and CNMs, if the services are typically and characteristically provided by physicians. In those instances where third-party payers do cover the services of NPs, PAs, and CNMs, the payments are most often indirect (i.e., to the employing physicians or institutions) rather than direct (i.e., to the NPs or CNMs). PAs have not sought direct payment. Some physicians are reluctant to hire these practitioners partly because of uncertainties about payment for their services.

The case study also reviews the evidence on the contributions of NPs, PAs, and CNMs to the health-care needs of the Nation. Although, most of the existing literature is not of very good methodological quality, the weight of the evidence indicates that NPs, PAs, and CNMs have positive influences on quality and access, that they could increase productivity and save costs, and that they have been accepted in a wide range of settings and under many different payment systems.

The effects of changing payment methods by extending coverage for the services of NPs, PAs, and CNMs and paying directly for the services of NPs and CNMs would undoubtedly be influenced by the market for their services. The health-care system is currently undergoing substantial changes in payment methods for other providers, in the supply of physicians, and in physicians' practice arrangements. These changes, along with the fact that an increasing proportion of the population is aged 65 or older, and thus in need of significant amounts of health-care services, have major implications for the employment and use of NPs, PAs, and CNMs and for health-care costs.

The uncertainty surrounding the market for the services of NPs, PAs, and CNMs in a health-care system in a state of flux makes any conclusions about the effects of payment changes very speculative. Nonetheless, it is

generally accurate to state that extending coverage for the services of NPs, PAs, and CNMs by additional payers would have little effect on the employment and use of these providers by health maintenance organizations or by hospitals for inpatient review.

Extending coverage and direct payment for the services of NPs and CNMs could encourage these providers to develop independent practices. If the overall volume of services did not increase, and if the NPs' and CNMs' payment levels were lower than physicians' levels for comparable services, third-party payers' costs might decrease. If the payment levels for comparable services were lower than those established for physicians and the difference were passed on to patients, patients costs would be lower. The extent of any savings would depend on what payment levels were established. In any event, patients could choose from a wider range of providers and might have greater access to primary-care services.

How extending coverage for the services of NPs, PAs, and CNMs and providing direct payment for NP and CNM services would affect costs and the employment and use of these practitioners in fee-for-service settings is unclear. By increasing the opportunities for NPs, PAs, and CNMs to provide care, however, extended coverage, with or without providing direct payment, would benefit individuals in certain locales (geographically underserved areas), certain settings (e.g., nursing homes), and specific populations (e.g., some disabled pregnant women and chronically ill patients who require home care) where health-care services are currently inaccessible or inadequate.

Prepared by: Office of Technology Assessment. Published in December 1986 as Case Study #37 (88 pp., 260 refs.) (Washington, D.C.: U.S. Government Printing Office, December 1986).

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